IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs, v. SANDOZ INC. Defendant.	Civil Action No. 1:14–CV–03547-RMB-KMW
ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, and ASTRAZENECA AB, Plaintiffs, v. SAGENT PHARMACEUTICALS, INC. Defendant.	Civil Action No. 1:14–CV–05539-RMB-KMW **JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT**

Pursuant to Local Patent Rule 4.3 and the Court's Amended Scheduling Order dated January 21, 2015, Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, and AstraZeneca AB (collectively, "Plaintiffs" or "AstraZeneca"), and Defendants Sandoz Inc. ("Sandoz") and Sagent Pharmaceuticals, Inc. ("Sagent") (collectively, "Defendants"), submit this Joint Claim Construction and Prehearing Statement for U.S. Patent Nos. 6,774,122 ("the '122 Patent"), 7,456,160 ("the '160 Patent"), 8,329,680 ("the '680 Patent"), and 8,466,139 ("the '139 Patent") (collectively, "the Patents-in-Suit") in the above-captioned matters, which have been consolidated for discovery purposes only.

I. Background

In these Hatch-Waxman patent actions, Plaintiffs are asserting infringement of the Patents-in-Suit against Sandoz Inc. based on, *inter alia*,[1] Sandoz's submission of an ANDA seeking to market fulvestrant injectable; intramuscular (250 mg/5 mL (50 mg/mL)) before the expiration of the Patents-in-Suit and against Sagent based on Sagent's submission of an ANDA seeking to market fulvestrant injectable; intramuscular (250 mg/5 mL (50 mg/mL)) before the expiration of the Patents-in-Suit.

A. The '122 Patent

The '122 Patent includes two independent claims and seven dependent claims. AstraZeneca currently asserts Claims 1-5 and 9 of the '122 Patent ("the '122 Asserted Claims") against Defendants. Plaintiffs' Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b), dated Oct. 24, 2014, at 2-3 (Sandoz); Plaintiffs' Disclosure of Asserted Claims Pursuant to L. Pat. R.

[1] Sandoz Inc.'s position is that subject matter jurisdiction is proper only for claims filed under 35 U.S.C. § 271(e), and that there is no subject matter jurisdiction for any claim purportedly filed under §§ 35 U.S.C. 271(a), (b) or (c).

3.6(b), dated Dec. 12, 2014, at 2-3 (Sagent). The '122 Asserted Claims recite[2] (disputed terms underlined):

1. A method of treating a hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment an intra-muscular injection of a pharmaceutical formulation comprising fulvestrant, a mixture of 10% weight of ethanol per volume of formulation, 10% weight of benzyl alcohol per volume of formulation and 15% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle, whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection.

2. The method as claimed in claim 1 wherein the benign or malignant disease is breast cancer.

3. The method as claimed in claim 1 wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks after injection.

4. The method as claimed in claim 1 wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks after injection.

5. A method of treating a hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment an intra-muscular injection of a pharmaceutical formulation comprising fulvestrant, a mixture of 10% weight of ethanol per volume of formulation, 10% weight of benzyl alcohol per volume of formulation and 15% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle whereby the formulation comprises at least 45 $mgml^{-1}$ of fulvestrant.

9. The method as claimed in claim 5 wherein the benign or malignant disease is breast cancer.

B. The '160 Patent

The '160 Patent includes two independent claims and ten dependent claims. AstraZeneca currently asserts Claim 4 of the '160 Patent ("the '160 Asserted Claim") against Defendants. Plaintiffs' Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b), dated Oct. 24, 2014, at 3-4 (Sandoz); Plaintiffs' Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b), dated Dec. 12, 2014, at 3-4 (Sagent). The '160 Asserted Claim recites (disputed terms underlined):

[2] A certificate of correction was issued with respect to the '122 Patent on October 16, 2007. The '122 Asserted Claims described herein incorporate the corrections.

1. (Not asserted; included for reference only)

A method of treating a hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment an intra-muscular injection of a pharmaceutical formulation comprising fulvestrant, a mixture of from 10 to 30% weight of ethanol and benzyl alcohol per volume of formulation and 10 to 25% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle, whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection.

2. (Not asserted; included for reference only)

A method of treating a hormonal dependent benign or malignant disease of the breast or reproductive tract by administration to a human in need of such treatment an intra-muscular injection of a pharmaceutical formulation comprising fulvestrant, a mixture of from 10 to 30% weight of a mixture of ethanol and benzyl alcohol per volume of formulation and from 10 to 25% weight of benzyl benzoate per volume of formulation and a sufficient amount of a castor oil vehicle, whereby the formulation comprises at least 45 $mgml^{-1}$ of fulvestrant.

4. The method as claimed in claim 1 or 2 wherein the formulation comprises a mixture of from 8.5 to 11.5% weight of ethanol per volume of formulation and from 8.5 to 11.5% weight of benzyl alcohos [sic] per volume of formulation an [sic] 12 to 18% weight of benzyl benzoate per volume of formulation.

C. The ’680 Patent

The ’680 Patent includes two independent claims and eighteen dependent claims. AstraZeneca currently asserts Claims 1-7 and 17 of the ’680 Patent (“the ’680 Asserted Claims”) against Defendants. Plaintiffs’ Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b), dated Oct. 24, 2014, at 5-6 (Sandoz); Plaintiffs’ Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b), dated Dec. 12, 2014, at 5-6 (Sagent). The ’680 Asserted Claims recite (disputed terms underlined):

1. A method for treating a hormonal dependent benign or malignant disease of the breast or reproductive tract comprising administering intramuscularly to a human in need of such treatment a formulation comprising:
about 50 $mgml^{-1}$ of fulvestrant;
about 10% w/v of ethanol;
about 10% w/v of benzyl alcohol;
about 15% w/v of benzyl benzoate; and

a sufficient amount of castor oil vehicle;
wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least four weeks.

2. The method of claim 1, wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$.

3. The method of claim 1, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer.

4. The method of claim 1, wherein the method comprises administering intramuscularly to a human in need of such treatment 5 mL of the formulation.

5. The method of claim 1, wherein the method further comprises once monthly administration of the formulation.

6. The method of claim 2, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer.

7. The method of claim 6, wherein the method comprises administering intramuscularly to a human in need of such treatment 5 mL of the formulation.

17. The method according to claim 1, wherein the formulation is administered in a divided dose.

D. The '139 Patent

The '139 Patent includes two independent claims and eighteen dependent claims. AstraZeneca currently asserts Claims 2, 3, 10, 12, 13 and 20 of the '139 Patent ("the '139 Asserted Claims") against Defendants. Plaintiffs' Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b), dated Oct. 24, 2014, at 6-8 (Sandoz); Plaintiffs' Disclosure of Asserted Claims Pursuant to L. Pat. R. 3.6(b), dated Dec. 12, 2014, at 6-8 (Sagent). The '139 Asserted Claims recite (disputed terms underlined):

1. (Not asserted; included for reference only)

A method for treating a hormonal dependent benign or malignant disease of the breast or reproductive tract comprising administering intramuscularly to a human in need of such treatment a formulation comprising:
about 50 $mgml^{-1}$ of fulvestrant;
a mixture of from 17-23% w/v of ethanol and benzyl alcohol;
12-18% w/v of benzyl benzoate; and
a sufficient amount of castor oil vehicle;

wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks.

2. The method of claim 1, wherein formulation comprises a mixture of from 19-21% w/v of ethanol and benzyl alcohol and 14-16% w/v of benzyl benzoate.

3. The method of claim 1, wherein formulation comprises:
about 10% w/v of ethanol;
about 10% w/v of benzyl alcohol; and
about 15% w/v of benzyl benzoate.

10. The method of claim 3, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer and the blood plasma fulvestrant concentration is attained for at least 4 weeks.

11. (Not asserted; included for reference only)

A method for treating a hormonal dependent benign or malignant disease of the breast or reproductive tract comprising administering intramuscularly to a human in need of such treatment a formulation consisting essentially of:
about 50 $mgml^{-1}$ of fulvestrant;
a mixture of from 17-23% w/v of ethanol and benzyl alcohol;
12-18% w/v of benzyl benzoate; and
a sufficient amount of castor oil vehicle;
wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks.

12. The method of claim 11, wherein formulation consists essentially of a mixture of from 19-21% w/v of ethanol and benzyl alcohol and 14-16% w/v of benzyl benzoate.

13. The method of claim 11, wherein formulation consists essentially of:
about 10% w/v of ethanol;
about 10% w/v of benzyl alcohol; and
about 15% w/v of benzyl benzoate.

20. The method of claim 13, wherein the hormonal dependent benign or malignant disease of the breast or reproductive tract is breast cancer and the blood plasma fulvestrant concentration is attained for at least 4 weeks.

II. Local Patent Rule 4.3

A. Construction of Claim Terms on Which the Parties Agree (L. Pat. R. 4.3(a))

In accordance with L. Pat. R. 4.3(a), the parties identify the following claim constructions on which they agree:

Patent and Claim No.	Claim Term	Agreed-upon Construction
’122 Patent, Claims 1-5 (Also applicable to Dep. Cl. 9) ’160 Patent, Claims 1 (not asserted), 2 (not asserted) (Also applicable to Dep. Cl. 4)	“pharmaceutical formulation”	Plain and ordinary meaning
’122 Patent, Claims 1-5 (Also applicable to Dep. Cl. 9) ’160 Patent, Claims 1 (not asserted), 2 (not asserted) (Also applicable to Dep. Cl. 4) ’680 Patent, Claim 1 (Also applicable to Dep. Cl. 2-7 and 17) ’139 Patent, Claims 1 (not asserted), 11 (not asserted) (Also applicable to Dep. Cl. 2, 3, 10, 12, 13 and 20)	“comprising”	Plain and ordinary meaning under patent law
’122 Patent, Claims 1-5 (Also applicable to Dep. Cl. 9) ’160 Patent, Claims 1 (not asserted), 2 (not asserted), 4 ’139 Patent, Claims 1 (not asserted), 2, 11 (not asserted), 12 (Also applicable to Dep. Cl. 2, 3, 10, 13 and 20)	“a mixture of”	Plain and ordinary meaning
’122 Patent, Claims 1, 3, 4 ’160 Patent, Claims 1 (not asserted) (Also applicable to Dep. Cl. 4)	“after injection”	“subsequent to injection”
’680 Patent, Claims 1 (Also applicable to Dep. Cl. 2-7 and 17) ’139 Patent, Claims 3, 11, and 13 (Also applicable to Dep. Cl. 10, 12, 20)	“about”	“approximately”
’680 Patent, Claim 4	“once monthly administration”	Plain and ordinary meaning
’680 Patent, Claim 17	“divided dose”	Plain and

Patent and Claim No.	Claim Term	Agreed-upon Construction
		ordinary meaning
'139 Patent, Claims 11 (not asserted), 12, and 13 (Also applicable to Dep. Cl. 20)	"consisting essentially of"/"consists essentially of"	Plain and ordinary meaning under patent law

B. Each Party's Proposed Construction of Each Disputed Term and Identification of Intrinsic and Extrinsic Evidence (L. Pat. R. 4.3(b))

In accordance with L. Pat. R. 4.3(b), the parties provide attached Exhibits A-D, which contain a table comparing Plaintiffs' and Defendants' proposed constructions for each disputed term in the '122 Patent (Exhibit A), the '160 Patent (Exhibit B), the '680 Patent (Exhibit C), and the '139 Patent (Exhibit D). Exhibits A-D identify, for each party, all intrinsic evidence the party contends supports its proposed construction and any extrinsic evidence known to the party on which it intends to rely either to support its proposed construction or to oppose any other party's proposed construction.

C. Identification of Most Significant Terms (L. Pat. R. 4.3(c))

1. Plaintiffs' Statement

Local Patent Rule 4.3(c) requires the parties to identify the terms whose construction will be most significant to the resolution of the case, and whether any disputed terms will be case or claim dispositive, or substantially conducive to promoting settlement.

At this time, Plaintiffs do not believe that the construction of any disputed term will resolve issues of infringement, nor that the construction of the disputed terms will be case or claim dispositive, or substantially conducive to promoting settlement. Plaintiffs understand that Defendants are arguing claim construction impacts validity issues.

2. Sandoz Inc.'s Statement

Sandoz Inc. states that the most significant term is "fulvestrant" because it is outcome determinative of the validity of every asserted claim. Other terms that bear on the validity of many of the claims of the Patents-in-Suit are "ethanol"; "a sufficient amount of castor oil"; "hormonal dependent benign or malignant disease of the breast or reproductive tract"; and "administration to a human in need of such treatment/a human in need of such treatment."

3. Sagent's Statement

At this time, Sagent does not believe that the construction of the disputed terms will be case or claim dispositive, or substantially conducive to promoting settlement. Sagent further states that many of the disputed terms, including "fulvestrant," "ethanol," "a sufficient amount of castor oil," and "hormonal dependent benign or malignant disease of the breast or reproductive tract" will be relevant to issues of validity.

D. Anticipated Length of Time Necessary for Claim Construction Hearing

In accordance with L. Pat. R. 4.3(d), the parties anticipate that the claim construction hearing will require no more than one day.

E. Anticipated Witnesses to be Called at Claim Construction Hearing

1. Plaintiffs' Statement

In accordance with L. Pat. R. 4.3(e), Plaintiffs identify Dr. Lisbeth Illum, Dr. Marc Lippman, Dr. John Robertson, and Dr. Ronald Sawchuk as expert witnesses that Plaintiffs may call at the Claim Construction Hearing to provide testimony to support their proposed constructions and/or to oppose Defendants' proposed constructions, to provide background information and scientific explanation as to the state of the art and the knowledge of a person of ordinary skill at the time of the invention, and/or to address the meanings of claim terms as understood by a person of ordinary skill in the art.

Dr. Lippman and/or Dr. Robertson may provide affirmative or rebuttal testimony, including as to the meaning of the following claim terms to a person of ordinary skill in the art at the time of invention, in the context of the Patents-in-Suit: hormonal dependent benign or malignant disease of the breast or reproductive tract; administration to a human in need of such treatment/a human in need of such treatment; fulvestrant; whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks; wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks; wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks; wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least four weeks; wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$; wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks; wherein . . . the blood plasma fulvestrant concentration is attained for at least 4 weeks. *See* attached Exhibits A-D.

Dr. Illum and/or Dr. Sawchuk may provide affirmative or rebuttal testimony, including as to the meaning of the following claim terms to a person of ordinary skill in the art at the time of invention, in the context of the Patents-in-Suit: fulvestrant; formulation; 10% (weight of ethanol per volume of formulation);[3] ethanol; 10% (weight of benzyl alcohol per volume of formulation); 15% (weight of benzyl benzoate per volume of formulation); sufficient amount of a castor oil vehicle; whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks (after injection); wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks (after injection); wherein the blood

[3] The parties included the "weight . . . volume . . . " or "w/v . . . " portions of the disputed claim terms in their Preliminary Lists of Claim Terms for Construction, exchanged on February 13, 2015, by agreement of the parties. During the parties meet and confer on March 9, 2015, the parties agreed that the "weight . . . volume . . . " or "w/v . . . " portions of the disputed claim terms did not need construction. As such, the "weight . . . volume . . . " or "w/v . . . " portions of the disputed claim terms listed herein do not have to be construed.

plasma fulvestrant concentration is attained for 2 to 5 weeks (after injection); from 8.5 to 11.5% (weight of ethanol per volume of formulation); from 8.5 to 11.5% (weight of benzyl alcohol per volume of formulation); 12 to 18% (weight of benzyl benzoate per volume of formulation); wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least four weeks; wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$; from 19-21% (w/v of ethanol and benzyl alcohol); 14-16% (w/v of benzyl benzoate); wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks; wherein . . . the blood plasma fulvestrant concentration is attained for at least 4 weeks. *See* attached Exhibits A-D.

2. Sandoz Inc.'s Statement

In accordance with L. Pat. R. 4.3(e), Sandoz identifies Dr. Paul Myrdal, Dr. Michael Mayersohn, Dr. Philip Gould and Dr. Divyesh Mehta as expert witnesses that Sandoz Inc. may call at the Claim Construction Hearing to provide testimony to support its proposed constructions and/or to oppose Plaintiffs' proposed constructions; to provide background information and scientific explanation as to the state of the art and the knowledge of a person of ordinary skill at the time of the invention; and/or to address the meanings of claim terms as understood by a person of ordinary skill in the art.

If necessary, Dr. Myrdal may provide affirmative or rebuttal testimony, including as to the meaning of the following claim terms to a person of ordinary skill in the art at the time of invention, in the context of the Patents-in-Suit: "formulation"/"pharmaceutical formulation"; and/or "ethanol"; and/or "sufficient amount of a castor oil vehicle."

If necessary, Dr. Mayersohn may provide affirmative or rebuttal testimony, including as to the meaning of the following claim terms to a person of ordinary skill in the art at the time of invention, in the context of the Patents-in-Suit: "whereby a therapeutically significant blood

plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks" and all other "blood plasma fulvestrant concentration" terms.

If necessary, Dr. Gould may provide affirmative or rebuttal testimony, including as to the meaning of the following claim terms to a person of ordinary skill in the art at the time of invention, in the context of the Patents-in-Suit: "formulation"/"pharmaceutical formulation"; and/or "ethanol"; and/or "sufficient amount of a castor oil vehicle"; and/or "fulvestrant"; and/or "10% (weight of ethanol per volume of formulation)"; and/or "10% (weight of benzyl alcohol per volume of formulation)"; and/or "15% (weight of benzyl benzoate per volume of formulation)"; and/or "from 8.5 to 11.5% (weight of ethanol per volume of formulation)"; and/or "from 8.5 to 11.5% (weight of benzyl alcohol per volume of formulation)"; and/or "12 to 18% (weight of benzyl benzoate per volume of formulation)"; and/or "from 19-21% (w/v of ethanol and benzyl alcohol)"; and/or "14-16% (w/v of benzyl benzoate)."

If necessary, Dr. Mehta may provide affirmative or rebuttal testimony, including as to the meaning of the following claim terms to a person of ordinary skill in the art at the time of invention, in the context of the Patents-in-Suit: "hormonal dependent benign or malignant disease of the breast or reproductive tract" and/or "human in need of such treatment."

3. Sagent's Statement

In accordance with L. Pat. R. 4.3(e), Sagent identifies Dr. Edmund Elder as an expert witness that Sagent may call at the Claim Construction Hearing to provide testimony in response to AstraZeneca's proposed constructions and/or in response to any testimony offered by AstraZeneca regarding its proposed constructions, to provide background information and scientific explanation as to the state of the art and the knowledge of a person of ordinary skill at the time of the invention, and/or to address the meanings of claim terms as understood by a person of ordinary skill in the art.

Dr. Elder may provide testimony, including as to the meaning of the following claim terms to a person of ordinary skill in the art at the time of invention, in the context of the Patents-in-Suit: fulvestrant; formulation; pharmaceutical formulation; administration to a human in need of such treatment; ethanol; sufficient amount of a castor oil vehicle; whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml-1 is attained for at least 2 weeks (after injection); wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks (after injection); wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks (after injection); wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml-1 for at least four weeks; wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 ngml-1; wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 ngml-1 for at least two weeks; wherein . . . the blood plasma fulvestrant concentration is attained for at least 4 weeks. *See* attached Exhibits A-D.

Respectfully submitted,

Dated: March 23, 2015

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EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"hormonal dependent benign or malignant disease of the breast or reproductive tract"	Plain and ordinary meaning to a person of skill in the art. **Intrinsic Evidence**[4] • The claims provide context and are self-limiting as the "method of treatment" requires administering "a pharmaceutical formulation" by "intra-muscular injection" to "a human in need of such treatment." • '122 Patent col.1, ll.16-18. • '122 Patent col.2, ll.3-10. • '122 Patent col.11, ll.18-22, 27-30. • '122 Patent PH, Office Action (Aug. 8, 2001). • '122 Patent PH, Response (Feb. 1, 2002). • '122 Patent PH, Office Action (Dec. 3, 2002). • '122 Patent PH, Response (June 3, 2003). • '122 Patent PH, Office Action (Aug. 27, 2003).	Various words of phrases within the claim term have a plain and ordinary meaning. However, the arrangement of the words within this claim term renders the term "benign or malignant disease" to be redundant. To the extent that this term is not redundant, the claim term is indefinite. Moreover, "hormonal dependent" is a term of degree. The Federal Circuit has held that for terms of degree, they must be defined or clarified in the specification or claim to identify more than merely *some* standard for measuring the scope of the term of degree phrase, and that a failure to do so renders the term indefinite. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014). Here, the specification and claim renders no guidance as to the scope of hormonal dependency required, instead, it depends on the unpredictable vagaries of any one	Certain terms and phrases have a plain and ordinary meaning, while other terms and phrases, for example, "hormonal dependent" and/or "disease of the breast or reproductive tract" are indefinite in light of failure of the intrinsic record to provide necessary guidance as to the scope and meaning of these terms and phrases. **Intrinsic Evidence**[6] • '122 Patent col.11, ll.1-6. • '122 Patent col.11, ll.18-22. • '122 Patent col.11, ll.27-29. • '122 Patent Claims 1, 2, 5, 9. • '160 Patent col.11, ll.4-8. • '160 Patent col.11, ll.21-25. • '160 Patent col.11, ll.30-32. • '160 Patent Claims 1, 2, 12. • '680 Patent col.11, ll.11-17. • '680 Patent col.11, ll.28-32. • '680 Patent col.11, ll.37-39. • '680 Patent Claims 1, 3, 6, 9, 11, 14.

[4] Plaintiffs reserve the right to rely on the entire intrinsic record, including any portion of the specification, prosecution history and intrinsic prior art references cited therein, to support or rebut proposed claim construction positions. Plaintiffs may also rely on evidence identified by Defendants in support of their constructions, and on expert testimony to rebut Defendants' proposed meanings, expert testimony, or other extrinsic evidence, if any, offered by Defendants in support of their claim constructions. Because the '122, '160, '680, and '139 Patent specifications are nearly identical, AstraZeneca cites and incorporates by reference to the '122 Patent specification, the corresponding support in the '160, '680, and '139 Patent specifications.

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	• '160 Patent PH, Second Information Disclosure Statement (Oct. 18, 2004). • '160 Patent PH, Response (Aug. 21, 2008). • M. Dukes et al., *Antiuterotrophic effects of the pure antioestrogen ICI 182,780 in adult female monkeys (*Macaca nemestrina*): quantitative magnetic resonance imaging*, 138 J. Endocrinol. 203 (1993). • U.S. Patent No. 5,733,902. **Extrinsic Evidence** • Valerie L. Baker & Robert B. Jaffe, *Clinical Uses of Antiestrogens*, 51 Obstet. Gyn. Survey 45 (1996). • D. M. Barnes et al., *Triple Hormone-Receptor Assay: A More Accurate Predictive Tool*	person's opinion; therefore, the claim term is indefinite. *Id.* at 1371. **Intrinsic Evidence**[5] • '122 Patent col.11, ll.18-22. • '122 Patent col.11, ll.27-29. • '122 Patent Claims 1, 2, 5, 9. • '160 Patent col.11, ll.21-25. • '160 Patent col.11, ll.30-32. • '160 Patent Claims 1, 2, 12. • '680 Patent col.11, ll.28-32. • '680 Patent col.11, ll.37-39. • '680 Patent Claims 1, 3, 6, 9, 11, 14. • '139 Patent col.10, ll.63-67. • '139 Patent col.11, ll.5-7. • '139 Patent Claims 1, 5, 10, 11, 15, 20. • '122 Patent PH, Response to Restriction (Feb. 1, 2002). • '122 Patent PH, Second Information Disclosure Statement	• '139 Patent col.10, ll.46-52. • '139 Patent col.10, ll.63-67. • '139 Patent col.11, ll.5-7. • '139 Patent Claims 1, 5, 10, 11, 15, 20. • '122 Patent PH, Office Action (Dec. 3, 2002). • '122 Patent PH, Amendment (June 3, 2003). • '160 Patent PH, Amendment and/or Gellert Declaration (Aug. 21, 2008). • '680 Patent, Office Action (Dec. 21, 2010). **Extrinsic Evidence** • *Taber's Medical Dictionary* 212, 1156, 1895 (Clayton L. Thomas, ed., 18 ed. 1997). • *Dorland's Illustrated Medical Dictionary* 191, 982 (28th ed. 1994).

[6] Sagent reserves the right to rely on the entire intrinsic record, including any portion of the specification, prosecution history and intrinsic prior art references cited therein, to support or rebut proposed claim construction positions. Sagent may also rely on the evidence identified by AstraZeneca and Sandoz in support of their constructions, and on expert testimony to rebut AstraZeneca's proposed meanings, expert testimony and other intrinsic and extrinsic evidence offered by AstraZeneca.

[5] Sandoz Inc. reserves the right to rely on the entire intrinsic record, including any portion of the specification, prosecution history and intrinsic prior art references cited therein, to support or rebut proposed claim construction positions. Sandoz Inc. may also rely on intrinsic and extrinsic evidence identified by Plaintiffs in support of their constructions; on expert testimony to rebut Plaintiffs' proposed meanings; and on expert testimony or other evidence, if any, offered by Plaintiffs in support of their own claim constructions.

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	for the Treatment of Advanced Breast Cancer, 40 Br. J. Cancer 862 (1979). • M. Carr et al., *Determination of oestrogen responsiveness of breast cancer by competitive reverse transcription-polymerase chain reaction*, 72 British J. Cancer 1427 (1995). • Surinder K. Chander et al., *The Biological Evaluation of Novel Antioestrogens for the Treatment of Breast Cancer*, 15 Crit. Rev. Oncol. Hematol. 243 (1993). • Dowsett et al., *Effects of the Pure Anti-Oestrogen ICI 182780 on Oestrogen Receptors, Progesterone Receptors and Ki67 Antigen in Human Endometrium* in Vivo, 10 Human Reproduction 262 (1995). • Gale M. England & V. Craig Jordan, *Pure Antiestrogens as a New Therapy for Breast Cancer*, 9 Oncol. Res. 397 (1997). • E. Enmark & J.A. Gustafsson, *Oestrogen Receptors - an Overview*, 246 J. Internal Med. 133 (1999). • H.J. Harmsen & A.J. Porsius,	("IDS") (Sept. 13, 2002). • '122 Patent PH, Office Action (Dec. 3, 2002). • '122 Patent PH, Amendment (June 3, 2003). • '122 Patent PH, Notice of Allowance (Mar. 24, 2004). • '160 Patent PH, Second IDS (Oct. 18, 2004). • '160 Patent PH, Amendment (Aug. 21, 2008). • M. Dukes et al., *Antiuterotrophic effects of the pure antioestrogen ICI 182,780 in adult female monkeys (*Macaca nemestrina*): quantitative magnetic resonance imaging*, 138 J. Endocrinol. 203 (1993). • John C. Waterton et al., *A Case of Adenomyosis in a Pigtailed Monkey Diagnosed by Magnetic Resonance Imaging and Treated with the Novel Pure Antiestrogen, ICI 182,780*, 43 Lab. Animal Sci. 247 (1993). • U.S. Patent No. 5,733,902. • U.S. Patent No. 3,541,209. • U.S. Patent No. 4,888,331. • European Patent Application No. EP 0 310 542 A1.	• *Reproductive System*, Merriam-Webster Medical Dictionary, http://www.merriam-webster.com/medical/reproductive%20system (last visited Feb. 25, 2015). • *Stedman's Medical Dictionary* 197, 1058, 1550 (Maureen Barlow Pugh et al. eds., 28th ed. 2000). • *PDR Medical Dictionary* 1831 (Marjory Spraycar et al. eds., 1995). • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	Endocrine Therapy of Breast Cancer, 24 Eur. J. Cancer Clin. Oncol. 1099 (1988). • Teresa G. Hayes et al., *Current Guidelines for the Diagnosis and Treatment of Breast Cancer*, 3 Dis. Manage Health Outcomes 239 (1998). • Stephen M. Holliday & Diana Faulds, *Management of Advanced Breast Cancer: Defining the Role of Toremifene*, 3 Dis. Manage Health Outcomes 143 (1998). • T. Scott Jennings & William T. Creasman, *Effects on the Reproductive Tract: Clinical Aspects, in Estrogens and Antiestrogens: Basic and Clinical Aspects* 223 (Robert Lindsay ed., 1997). • Elwood V. Jensen, *Steroid Hormones, Receptors, and Antagonists*, 784 Annals of N.Y. Acad. Sci. 1 (1996). • Elwood V. Jensen, *Estrogen Receptors in Hormone-dependent Breast Cancers*, 35 Cancer Res. 3362 (1975). • Ann Johnson, *The Hormonal Manipulation of Breast Cancer*, 8	• International Patent Application No. WO 99/27906. **Extrinsic Evidence** • Surinder K. Chander et al., *The Biological Evaluation of Novel Antioestrogens for the Treatment of Breast Cancer*, 15 Crit. Rev. Oncol. Hematol. 243 (1993). • S. Chatterjee & D.C. Johnson, *Contrasting Action of Antiestrogen (ICI-182780) for Preventing Initiation of Embryo Implantation by Estradiol or Epidermal Growth Factor (EGF)*, 53 Life Sci. 1625 (1993). • M. Dowsett et al., *Effects of the Pure Anti-oestrogen ICI 182780 on Oestrogen Receptors, Progesterone Receptors and Ki67 Antigen in Human Endometrium* In Vivo, 10 Human Reproduction 262 (1995). • Ruth M. O'Regan et al., *Effects of the Antiestrogens Tamoxifen, Toremifene, and ICI 182,780 on Endometrial Cancer Growth*, 90 J. Nat'l Cancer Inst. 1552 (1998). • Edward C. Reifenstein, Jr., *Hydroxyprogesterone Caproate*	

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	J. Nutr. Environ. Med. 177 (1998) • R.E. Leake, *Clinical aspects of steroid receptor assays*, 41 Med. Lab. Sci. 257 (1984). • Sewa S. Legha, *Tamoxifen in the Treatment of Breast Cancer*, 109 Annals of Internal Med. 219 (1988). • P. Lombardi et al., *Ovarian function suppression with a GnRH analogue: D-ser(But[t])[6]-Arzgly[10]-LHRH (Goserelin) in hormone dependent canine mammary cancer*, 22 J. Vet. Pharmacol. Therap. 56 (1999). • C. Kent Osborne, *Steroid hormone receptors in breast cancer management*, 51 Br. Cancer Res. Tr. 227 (1998). • C. Kent Osborne et al., *The Value of Estrogen and Progesterone Receptors in the Treatment of Breast Cancer*, 46 Cancer 2884 (1980). • Kathleen Pritchard, *Effects on Breast Cancer: Clinical Aspects, in Estrogens and Antiestrogens: Basic and Clinical Aspects* 175 (Robert Lindsay ed., 1997).	*Therapy in Advanced Endometrial Cancer*, 27 Cancer 485 (1971). • *Taber's Medical Dictionary* (Clayton L. Thomas, ed., 18 ed. 1997). • Alan E. Wakeling & Jean Bowler, *ICI 182,780, A New Antioestrogen with Clinical Potential*, 43 J. Steroid Biochemistry & Molecular Biol. 173 (1992). • U.S. Patent No. 4,310,523. • U.S. Application Publication No. 2001/0056086 A1. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term. • If necessary, an expert(s) will testify that the claim term "hormonal dependent benign or malignant disease of the breast or reproductive tract" did not have a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence.	

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	• A. Ravaioli et al., *Prognosis and prediction of response in breast cancer: the current role of the main biological markers*, 31 Cell Prof. 113 (1998). • Angelika Reiner et al., *Immunocytochemical Localization of Estrogen and Progesterone Receptor and Prognosis in Human Primary Breast Cancer*, 50 Cancer Res. 7057 (1990). • Jerome P. Richie, *Anti-Androgens and other Hormonal Therapies for Prostate Cancer*, 54 Urology 15 (1999). • Simon P. Robinson & V. Craig Jordan, *Antiestrogenic Action of Toremifene on Hormone-dependent, -independent, and Heterogeneous Breast Tumor Growth in the Athymic Mouse*, 49 Cancer Res. 1758 (1989). • M. Seifert et al., *Estrogen replacement therapy in women with a history of breast cancer*, 32 Maturitas 63 (1999). • Gregory P. Sutton et al., *Estrogen and Progesterone Receptors in Epithelial Ovarian Malignancies*,		

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	23 Gyn. Oncol. 176 (1986). • Kazuto Takayama et al., *Treatment of severe postmenopausal endometriosis with an aromatase inhibitor*, 69 Fertility & Sterility 709 (1998). • Alan E. Wakeling & Jean Bowler, *ICI 182,780, A New Antioestrogen with Clinical Potential*, 43 J. Steroid Biochemistry & Molecular Biol. 173 (1992). • Jonathan Weintraub et al., *Evaluation of Estrogen Receptors by Immunocytochemistry on Fine-Needle Aspiration Biopsy Specimens from Breast Tumors*, 60 Cancer 1163 (1987). • U.S. Patent No. 4,728,640. • U.S. Patent No. 4,902,717. • U.S. Patent No. 5,434,146. • European Patent No. 0 195 015. • 64 Fed. Reg. 63,820 (Nov. 22, 1999). • If necessary, an expert(s) will testify that the claim term "hormonal dependent benign or malignant disease of the breast or reproductive tract" had a clear and definite meaning to a person		

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'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify as to the plain and ordinary meaning of "hormonal dependent benign or malignant disease of the breast or reproductive tract" in the context of the intrinsic evidence, including the evidence referred to above, and the expert(s) may discuss cancerous or non-cancerous diseases of the breast or reproductive system, such as breast cancer or endometriosis, their relationship to hormones such as estrogen, and the treatment of hormonal dependent and hormonal independent benign or malignant diseases of the breast or reproductive tract. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.		
"administration to a human in	Plain and ordinary meaning to a person of skill in the art—i.e.,	Plain and ordinary meaning – i.e., administration to a human having a	Plain and ordinary meaning – i.e., administration to a human having a

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
need of such treatment"	administration to a human with a disease (as limited by the claims) that could benefit from the method of treating. *See evidence for "hormonal dependent benign or malignant disease of the breast or reproductive tract" above.* **Intrinsic Evidence** • The claims provide context and are self-limiting as the "method of treatment" requires administering "a pharmaceutical formulation" by "intra-muscular injection" for the treatment of "hormonal dependent benign or malignant disease of the breast or reproductive tract." • '122 Patent col.1, ll.16-62. • '122 Patent col.2, ll.1-45. • '122 Patent col.11, ll.18-22, 27-30. **Extrinsic Evidence** • If necessary, an expert(s) will testify as to the plain and ordinary meaning of "administration to a human in need of such treatment"	hormonal dependent benign or malignant disease of the breast or reproductive tract. **Intrinsic Evidence** • '122 Patent PH, Second IDS (Sept. 13, 2002). • Michael Dukes et al., *Antiuterotrophic Effects of the Pure Antioestrogen ICI 182,780 in Adult Female Monkeys (*Macaca nemestrina*): Quantitative Magnetic Resonance Imaging*, 138 J. Endocrinology 203 (1993). • John C. Waterton et al., *A Case of Adenomyosis in a Pigtailed Monkey Diagnosed by Magnetic Resonance Imaging and Treated with the Novel Pure Antiestrogen, ICI 182,780*, 43 Lab. Animal Sci. 247 (1993). • U.S. Patent No. 5,733,902. • U.S. Patent No. 4,888,331. • U.S. Patent No. 3,541,209. • European Patent Application No. EP 0 310 542 A1. • International Patent Application No. WO 99/27906. **Extrinsic Evidence**	hormonal dependent benign or malignant disease of the breast or reproductive tract. To the extent "in need of such treatment" refers to "hormonal dependent benign or malignant disease of the breast or reproductive tract," Sagent incorporates its proposed constructions and intrinsic/extrinsic evidence citations accordingly. **Intrinsic Evidence** • '122 Patent col.11, ll.1-6. • '122 Patent col.11, ll.18-22. • '122 Patent col.11, ll.27-29. • '160 Patent col.11, ll.4-8. • '160 Patent col.11, ll.21-25. • '160 Patent col.11, ll.30-32. • '680 Patent col.11, ll.11-17. • '680 Patent col.11, ll.28-32. • '680 Patent col.11, ll.37-39. • '139 Patent col.10, ll.46-52. • '139 Patent col.10, ll.63-67. • '139 Patent col.11, ll.5-7. • '122 Patent PH, Office Action (Dec. 3, 2002). • '122 Patent PH, Amendment (June 3, 2003).

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	in the context of the intrinsic evidence, including the evidence referred to above. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.	• Surinder K. Chander et al., *The Biological Evaluation of Novel Antioestrogens for the Treatment of Breast Cancer*, 15 Crit. Rev. Oncol. Hematol. 243 (1993). • S. Chatterjee & D.C. Johnson, *Contrasting Action of Antiestrogen (ICI-182780) for Preventing Initiation of Embryo Implantation by Estradiol or Epidermal Growth Factor (EGF)*, 53 Life Sci. 1625 (1993). • M. Dowsett et al., *Effects of the Pure Anti-oestrogen ICI 182780 on Oestrogen Receptors, Progesterone Receptors and Ki67 Antigen in Human Endometrium* In Vivo, 10 Human Reproduction 262 (1995). • Ruth M. O'Regan et al., *Effects of the Antiestrogens Tamoxifen, Toremifene, and ICI 182,780 on Endometrial Cancer Growth*, 90 J. Nat'l Cancer Inst. 1552 (1998). • Edward C. Reifenstein, Jr., *Hydroxyprogesterone Caproate Therapy in Advanced Endometrial Cancer*, 27 Cancer 485 (1971). • Alan E. Wakeling & Jean Bowler, *ICI 182,780, A New Antioestrogen*	• '160 Patent PH, Amendment and/or Gellert Declaration (Aug. 21, 2008). • '680 Patent PH, Office Action (Dec. 21, 2010). **Extrinsic Evidence** • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		with Clinical Potential, 43 J. Steroid Biochemistry & Molecular Biol. 173 (1992). • U.S. Patent No. 4,310,523. • U.S. Application Publication No. 2001/0056086 A1. • If necessary, an expert(s) will testify as to the plain and ordinary meaning of "administration to a human in need of such treatment" in the context of the intrinsic evidence, including the evidence referred to above. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.	
"fulvestrant"	Plain and ordinary meaning to a person of skill in the art—i.e., the international non-proprietary name for the chemical compound, 7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol. **Intrinsic Evidence** • '122 Patent col.1, ll.65-67. • '122 Patent col.2, ll.1-2. • '122 Patent PH, Response (June	"7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol, including pharmaceutically acceptable salts thereof, and any possibly solvates of either thereof" **Intrinsic Evidence** • '122 Patent col.1, ll.1-15. • '122 Patent col.1, l.64-col.2, l.2. • '160 Patent col.1, ll.6-16. • '160 Patent col.1, l.65 – col 2, l.3.	"Fulvestrant (7α-[9-(4,4,5,5,5-pentafluropentylsulphinyl0nonyl]oestra-1,3,5(10)-triene-3,17β-diol) or a pharmaceutically acceptable salt or solvate thereof" **Intrinsic Evidence** • '122 Patent, Abstract. • '122 Patent col.1, ll.1-15. • '122 Patent col.1, l.64 – col.2, l.2 • '160 Patent, Abstract. • '160 Patent col.1, ll.6-16.

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'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	3, 2003). • '160 Patent PH, Second Information Disclosure Statement (Oct. 18, 2004). • '160 Patent PH, Response (Aug. 21, 2008). • '160 Patent PH, Declaration (Aug. 21, 2008). **Extrinsic Evidence** • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.	• '680 Patent col.1, ll.18-21. • '680 Patent col.1, l.65 – col.2, l.4. • '139 Patent col.1, ll.20-24. • '139 Patent col.2, ll.1-6. **Extrinsic Evidence** • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.	• '160 Patent col.1, l.65 – col.2, l.3. • '680 Patent, Abstract. • '680 Patent col.1, ll.18-21. • '680 Patent col.1, l.65 – col.2, l.4 • '139 Patent, Abstract. • '139 Patent col.1, ll.20-24 • '139 Patent col.2, ll.1-6. **Extrinsic Evidence** • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.
"10%" (weight of ethanol per volume of formulation)	"10%" (weight of pharmaceutically-acceptable ethanol per volume of formulation) **Intrinsic Evidence** • '122 Patent col.6, ll.27-32. • '122 Patent col.6, ll.65-67. • '122 Patent tbls.3, 4. • '122 Patent col.7, ll.1-11. • '122 Patent col.7, ll.33-42. • '122 Patent col.8, ll.6-21. • '122 Patent col.12, ll.15-35. • *Remington's Pharmaceutical Sciences* 69-103 (Alfonso Gennaro ed., 18th ed. 1990)	"Exactly 10%" (weight of ethanol per volume of formulation) **Intrinsic Evidence** • '122 Patent claims. • '160 Patent claims. • '680 Patent claims. • '139 Patent claims. • '160 Patent PH, Notice of Allowance (Oct. 6, 2008). • '680 Patent PH, Amendment Declaration (Jan. 17, 2012). **Extrinsic Evidence** • If necessary, an expert(s) will	

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	(hereinafter "*Remington's*").[7] **Extrinsic Evidence** • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of excipients, and that "10% weight of ethanol per volume of formulation" in the context of the intrinsic evidence, including the evidence referred to above and consistent with the ordinary meaning, means "10% weight of pharmaceutically-acceptable ethanol per volume of formulation." • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.	testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term. • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of excipients.	
"ethanol"	"pharmaceutically-acceptable ethanol of a quality such that it will meet pharmacopoeial standards (such as	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not	There are a number of concepts associated with the plain and ordinary meaning of ethanol, including but not

[7] To the extent Plaintiffs are asserting that the entirety of *Remington's Pharmaceutical Sciences* (Alfonso Gennaro ed., 18th ed. 1990) is intrinsic prior art for any of the Patents-in-Suit, Sandoz Inc. disputes this. The Patents-in-Suit, on their face, do not cite to *Remington's* in its entirety or even generally; rather, each Patent-in-Suit, on the face of and in its prosecution history file wrapper, discloses only a single page of *Remington's*. (*See generally* '122 Patent at cover (Other Publications); '160 Patent at cover (Other Publications); '680 Patent at cover (Other Publications); '139 Patent at cover (Other Publications); '122 Patent PH; '160 Patent PH, '680 Patent PH; '139 Patent PH.).

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	are described in the US, British, European and Japanese pharmacopoeias) and as such will contain some water and possibly other organic solvents, for example ethanol in the US Pharmacopeia contains not less than 94.9% by volume and not more than 96.0% by volume of ethanol when measured at 15.56° C, and dehydrated alcohol in the US Pharmacopeia contains not less than 99.5% ethanol by volume when measured at 15.56° C." **Intrinsic Evidence** • The claims provide context and are self-limiting as the "method of treatment" requires administering "a pharmaceutical formulation" by "intra-muscular injection" to "a human in need of such treatment." • '122 Patent col.5, ll.58-64. • '122 Patent col.6, ll.7-9, 17-21, 65-67. • '122 Patent col.7, ll.12-18, 33-42. • '122 Patent col.8, ll.1-22. • '122 Patent tbls.3, 4. • '122 Patent PH, Amendment, (Dec. 29, 2003).	limited to: • Pure ethanol; • ethanol containing "some water"; • ethanol containing "some other solvents"; • ethanol containing "some water" and "some other solvents"; • not less than 92.3 percent and not more than 93.8 percent, by weight, corresponding to not less than 94.9 percent and not more than 96.0 percent, by volume, at 15.56°, of C_2H_5OH; • not less than 99.2 percent, by weight, corresponding to not less than 99.5 percent, by volume, at 15.56°, of C_2H_5OH; • not less than 95.1 per cent *V/V* (92.6 per cent *m/m*) and not more than 96.9 per cent *V/V* (95.2 per cent *m/m*) of C_2H_6O (M_r 46.07) at 20°C, and water; • not less than 99.4% v/v or 99.0% w/w and not more than 100.0% v/v or 100.0% w/w of C_2H_5OH; • not less than 95.1 vol% and not more than 95.6 vol% (by specific gravity) of C_2H_6O at 15° C. The above list is not meant to be	limited to C_2H_5OH, dehydrated or pure ethanol, alcohol USP, alcohol USP, ≥ 99.5% v/v of C_2H_5OH, 95.1-95.6% v/v (by specific gravity) of C_2H_5OH at 15° C, or any commonly used form of ethanol or alcohol including in combination with various amounts of water and other solvents. **Intrinsic Evidence** • '122 Patent col.7, ll.32-42 • '122 Patent col.11, l.54 – col.12, l.12. • '122 Patent, tbl.3. • '160 Patent col.7, ll.48-57. • '160 Patent col.11, l.59–col.12, l.16. • '160 Patent, tbl.3. • '680 Patent col.7, l.62–col.8, l.4. • '680 Patent col.11, l.66–col.12, l.21. • '680 Patent, tbl.3. • '139 Patent col.7, ll.39-48. • '139 Patent col.11, ll.34-56. • '139 Patent, tbl.3. **Extrinsic Evidence** • *Handbook of Pharmaceutical Excipients* 7-9 (Arthur H. Kibbe,

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	• '160 Patent PH, Response (Aug. 21, 2008). • '160 Patent PH, Declaration (Aug. 21, 2008). **Extrinsic Evidence** • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, and that "ethanol" in the context of the intrinsic evidence, including the evidence referred to above means "pharmaceutically-acceptable ethanol." • If necessary, an expert(s) will testify that "ethanol" had a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will	comprehensive.[8] **Intrinsic Evidence** • '122 Patent col.7, ll.32-42; tbl.3. • '160 Patent col.7, ll.48-57; tbl.3. • '680 Patent col.7, l.62–col.8, l.4; tbl.3. • '139 Patent col.7, ll.39-48; tbl.3. • '680 Patent PH, Amendment Declaration (Jan. 17, 2012). • *Alcohol, in Martindale: The Complete Drug Reference* (Kathleen Parfitt ed., 32d ed. 1999). • *Ethyl Alcohol, in The Merck Index* (12th ed. 1996). • U.S. Patent No. 5,484,801. **Extrinsic Evidence** • *Alcohol, in United States Pharmacopeia 23, National Formulary 18* (1995). • *Dehydrated Alcohol, in United*	ed., 3d. ed. 2000). • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.

[8] Defendant Sandoz Inc. states that the presence of multiple plain and ordinary meanings of a claim term does not mean any one of these meanings is the correct construction of the term, and does not indicate any admission or acknowledgment by Sandoz that the claim term has a meaning that satisfies the requirement of 35 U.S.C. § 112, ¶ 2. Additionally, Sandoz Inc. reserves all rights to pursue various invalidity theories, including but not limited to indefiniteness theories under 35 U.S.C. § 112 for at least the reason that a person of ordinary skill in the art could read the term in various ways, as outlined above, and the appropriate scope of the claim language would change as a consequence. Moreover, the specification does not provide necessary guidance as to the appropriate scope and meaning to apply to this term, and nor does the prosecution history or other intrinsic evidence. Lastly, as the test for indefiniteness is still being developed and applied by the Federal Circuit following the U.S. Supreme Court's ruling in *Nautilus, Inc. v. Biosig Instruments, Inc*., Sandoz specifically reserves all rights to make additional, modified, or different arguments regarding the same.

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'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.	*States Pharmacopeia 23, National Formulary 18* (1995). • *Ethanol (96 per cent), in European Pharmacopoeia* (3d ed. Supp. 1999). • *Ethanol (96 per cent), in* 1 *British Pharmacopoeia* (1999). • *Ethanol (Absolute Alcohol; Dehydrated Alcohol), in* 1 *British Pharmacopoeia* (1993). • *Ethanol, in The Japanese Pharmacopoeia: JP XIII* (13th ed. 1996). • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process and the use of ethanol in same. • If necessary, an expert(s) will testify that "ethanol" had multiple plain and ordinary meanings to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.	

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'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"10%" (weight of benzyl alcohol per volume of formulation)	"10%" (weight of pharmaceutically-acceptable benzyl alcohol per volume of formulation) *See evidence for "10% weight of ethanol per volume of formulation" above.* **Extrinsic Evidence** • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of excipients, and that "10% weight of benzyl alcohol per volume of formulation" in the context of the intrinsic evidence, including the evidence referred to above and consistent with the ordinary meaning, means "10% weight of pharmaceutically-acceptable benzyl alcohol per volume of formulation." • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.	"Exactly 10%" (weight of benzyl alcohol per volume of formulation). **Intrinsic Evidence** • '122 Patent claims. • '160 Patent claims. • '680 Patent claims. • '139 Patent claims. • '160 Patent PH, Notice of Allowance (Oct. 6, 2008). • '680 Patent PH, Amendment Declaration (Jan. 17, 2012). **Extrinsic Evidence** • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of excipients. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.	
"15%" (weight of benzyl	"15%" (weight of pharmaceutically-acceptable benzyl benzoate per	"Exactly 15%" (weight of benzyl benzoate per volume of formulation).	

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
benzoate per volume of formulation)	volume of formulation) *See evidence for "10% weight of ethanol per volume of formulation" above.* **Intrinsic Evidence** • '122 Patent col.7, ll.43-67. **Extrinsic Evidence** • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of excipients, and that "15% weight of benzyl benzoate per volume of formulation" in the context of the intrinsic evidence, including the evidence referred to above and consistent with the ordinary meaning, means "15% weight of pharmaceutically-acceptable benzyl benzoate per volume of formulation." • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.	**Intrinsic Evidence** • '122 Patent claims. • '160 Patent claims. • '680 Patent claims. • '139 Patent claims. • '160 Patent PH, Notice of Allowance (Oct. 6, 2008). • '680 Patent PH, Amendment Declaration (January 17, 2012). **Extrinsic Evidence** • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of excipients. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.	
"sufficient	"after fulvestrant and the excipients,	There are multiple concepts that can	There are multiple concepts that can

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
amount of a castor oil vehicle"	the remaining volume is filled with pharmaceutically-acceptable castor oil" **Intrinsic Evidence** • The claims provide context and are self-limiting as the "method of treatment" requires administering "a pharmaceutical formulation" by "intra-muscular injection" to "a human in need of such treatment." • '122 Patent col.3, ll.62-64. • '122 Patent col.6, ll.27-33. • '122 Patent col.7, ll.28-31. • '122 Patent col.8, ll.23-28. • '122 Patent col.9, ll.30-47. • '122 Patent col.10, ll.1-23, 56-67. • '122 Patent col.11, ll.23-26, 57. • '122 Patent col.12, ll.4-12, 15-35. • '160 Patent PH, Response (Aug. 21, 2008). • '160 Patent PH, Declaration (Aug. 21, 2008). • '680 Patent PH, Response, at 9 (June 20, 2011). • U.S. Patent No. 5,183,814, col.11, ll.6-11. • *Remington's*, 69-103. • C. Riffkin et al., *Castor oil as a*	be associated with the plain and ordinary meaning(s), including but not limited to: • sufficient amount of a castor oil to solubilize the active ingredient; • sufficient amount of a castor oil to bring the composition to a certain volume; • sufficient amount of a castor oil to bring the composition to a certain weight; • sufficient amount of a castor oil needed to minimize precipitation of the injected formulation; • sufficient amount of a castor oil needed to render the injected formulation functional; • sufficient amount of a castor oil containing a particular proportion of triglycerides of ricinoleic acid; • sufficient amount of a particular grade of castor oil; • sufficient amount of a castor oil that conforms to a particular standard; • sufficient amount of a castor oil blended with other oils. The above list is not meant to be	be associated with the plain and ordinary meaning(s), including but not limited to: • sufficient amount of a castor oil to solubilize the active ingredient; • sufficient amount of a castor oil to bring the composition to a certain volume; • sufficient amount of a castor oil needed to minimize precipitation of the injected formulation; • sufficient amount of a castor oil needed to render the injected formulation functional; • sufficient amount of a castor oil containing a particular proportion of triglycerides of ricinoleic acid; • sufficient amount of a particular grade of castor oil; • sufficient amount of a castor oil that conforms to a particular standard; • sufficient amount of a castor oil blended with other oils. **Intrinsic Evidence** • '122 Patent, Abstract. • '122 Patent col.3, ll.61-64. • '122 Patent col.5, ll.58-67. • '122 Patent col.6, ll.7-26.

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'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	vehicle for parenteral administration of steroid hormones, 53 J. Pharm. Sci. 891-95 (1964). **Extrinsic Evidence** • A.J. Spiegel & M.M. Noseworthy, *Use of Nonaqueous Solvents in Parenteral Products*, 52 J. Pharmaceutical Sci. 917 (1963). • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of excipients, and that "sufficient amount of a castor oil vehicle" in the context of the intrinsic evidence, including the evidence referred to above and consistent with the ordinary meaning, means "after fulvestrant and the excipients are added, the remaining volume is filled with pharmaceutically-acceptable castor oil." • If necessary, an expert(s) will testify that "sufficient amount of	comprehensive.[9] **Intrinsic Evidence** • '122 Patent col.8, ll.23-28. • '122 Patent cols.9-10; tbls.3 & 4; Fig. 1. • '122 Patent col.2, ll.62-67. • '122 Patent col.3, ll.61-64. • '122 Patent col.6, ll.7-26. • '122 Patent col.7, ll.28-31. • '122 Patent col.11, ll.23-26. • '122 Patent col.11, ll.56-59. • '122 Patent col.12, ll.4-35. • '160 Patent col.8, ll.42-48. • '160 Patent cols.9-11; tbls.3 & 4; Fig. 1. • '160 Patent col.2, ll.62-67. • '160 Patent col.5, ll.1-3. • '160 Patent col.6, ll.28-40. • '160 Patent col.7, ll.44-47. • '160 Patent col.11, ll.26-29. • '160 Patent col.11, ll.60-63. • '160 Patent col.12, ll.9-50. • '680 Patent col.8, ll.52-57. • '680 Patent cols.9-11; tbls.3 & 4; Fig. 1. • '680 Patent col.2, ll.60-66. • '680 Patent col.3, ll.63-65.	• '122 Patent col.8, ll.23-28. • '122 Patent col.9, ll.23-28. • '122 Patent col.10, ll.27-67. • '122 Patent, tbls.3,4. • '122 Patent, fig.1. • '160 Patent, Abstract. • '160 Patent col.5, ll.1-5. • '160 Patent col.6, ll.4-13. • '160 Patent col.6, ll.20-40. • '160 Patent col.8, ll.43-48. • '160 Patent col.9, ll.41-48. • '160 Patent col.10, l.48 – col.11, l.3. • '160 Patent, tbls.3,4. • '160 Patent, fig.1. • '680 Patent, Abstract. • '680 Patent col.3, ll.63-66. • '680 Patent col.6, ll.19-27. • '680 Patent col.6, ll.34-53. • '680 Patent col.8, ll.52-58. • '680 Patent col.9, ll.45-51. • '680 Patent col.10, ll.43-45. • '680 Patent, tbls.3,4. • '680 Patent, fig.1. • '139 Patent, Abstract. • '139 Patent col.3, ll.55-60. • '139 Patent col.6, ll.1-9. • '139 Patent col.6, ll.16-35.

[9] *See supra* note 8, incorporated by reference herein.

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	a castor oil vehicle" had a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.	• '680 Patent col.6, ll.34-54. • '680 Patent col.7, ll.58-61. • '680 Patent col.11, ll.33-36. • '680 Patent col.11, l.67–col.12, l.3. • '680 Patent col.12, ll.15-21. • '139 Patent col.8, ll.28-33. • '139 Patent col.9-10; tbls.3 & 4; Fig. 1 • '139 Patent col.2, ll.61-67. • '139 Patent col.3, ll.55-57. • '139 Patent col.6, ll.16-36. • '139 Patent col.7, ll.35-38. • '139 Patent col.11, ll.1-4. • '139 Patent col.11, ll.35-38. • '139 Patent col.11, ll.50-56. • '160 Patent PH, Amendment & Declaration (Aug. 21, 2008). • '160 Patent PH, Notice of Allowance (Oct. 6, 2008). • '680 Patent PH, Amendment Declaration (Jan. 17, 2012). • C. Riffkin et al., *Castor oil as a vehicle for parenteral administration of steroid hormones*, 53 J. Pharm. Sci. 891 (1964). • U.S. Patent No. 5,183,814 • U.S. Patent No. 4,048,309. • U.S. Patent No. 4,048,310.	• '139 Patent col.8, ll.28-33. • '139 Patent col.9, ll.22-28. • '139 Patent col.10, ll.23-45. • '139 Patent, tbls.3,4. • '139 Patent, fig.1. • '122 Patent PH, Amendment (June, 3, 2003). • '160 Patent PH, Amendment (Aug. 21, 2008). • '680 Patent PH, Amendment (June 20, 2011). • '680 Patent PH, Office Action Dec. 21, 2010). • '680 Patent PH, Amendment and/or Sawchuk Declaration (Jan. 17, 2012). • Migally, *Effect of Castor Oil and Benzyl Benzoate Used as a Vehicle for Antiandrogens on the Adrenal Cortex*, 2 Archives Andrology, 365-369 (1979). **Extrinsic Evidence** • *Stedman's Medical Dictionary* 1935 (Maureen Barlow Pugh et al. eds., 28th ed. 2000). • *Vehicle*, Merriam-Webster Medical Dictionary, http://www.merriam-webster.com/medical/vehicle (last

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		• U.S. Patent No. 5,929,030. **Extrinsic Evidence** • Von W. Füller, *Vehikel und Hilfsmittel zur Herstellung von Injektionslösungen von Steroidhormonen*, 47 Pharmaceutica Acta Helvetiae 449 (1972) (Certified Translation Aug. 29, 2014). • Plaintiffs' Responses to Defendant Sandoz's Invalidity Contentions. • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of excipients. • If necessary, an expert(s) will testify that "sufficient amount of a castor oil vehicle" did not have a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.	visited Feb. 25, 2015). • *Dorland's Illustrated Medical Dictionary* 1799 (28th ed. 1994). • *Taber's Medical Dictionary* 2069 (Clayton L. Thomas, ed., 18 ed. 1997). • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.

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'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks (after injection)"	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 2 weeks" **Intrinsic Evidence** • The claims provide context and are self-limiting as the "method of treatment" requires administering "a pharmaceutical formulation" by "intra-muscular injection" to "a human in need of such treatment" • '122 Patent col.1, ll.4-5. • '122 Patent col.5, ll.58-67. • '122 Patent col.6, ll.1-6. • '122 Patent col.10, ll.27-67. • '122 Patent col.9, ll.1-4, 7-14. • '122 Patent col.11, ll.4-9. • '122 Patent Fig. 1. • '160 Patent PH, Response (Aug. 21, 2008). • '160 Patent PH, Declaration (Aug. 21, 2008). • '680 Patent PH, Response (June 20, 2011). • '680 Patent PH, Response (Jan. 17, 2012). • '680 Patent PH, Declaration (Jan. 17, 2012).	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any point within two weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any number of points within two weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is maintained by the patient in question for the entirety of two weeks after injection; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by the patient in question for the entirety of two weeks after injection; • whereby the mean therapeutically effective blood plasma	There are a number of concepts associated with the plain and ordinary meaning, including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any point within two weeks; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any number of points within two weeks; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is maintained by any patient for the entirety of two weeks; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by any patient for the entirety of two weeks; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	• *Remington's*, at 1676-93. • *Remington's*, at 1451-58. **Extrinsic Evidence** • *The Theory and Practice of Industrial Pharmacy* 430-456 (Leon Lachman ed., 3d ed. 1986). • Howard C. Ansel et al., *Pharmaceutical Dosage Forms and Drug Delivery Systems* 100-141 (7th ed. 1999) (hereinafter "Ansel"). • E4 Guideline for Industry Dose-Response Information to Support Drug Registration, 59 Fed. Reg. 55,972 (Nov. 9, 1994). • E8 General Considerations for Clinical Trials, 62 Fed. Reg. 66,113 (Dec. 17, 1997). • Peter Goldman, *Rate-Controlled Drug Delivery*, 307 New Eng. J. Med. 286 (1982). • Jan Koch-Weser, *Serum Drug Concentrations as Therapeutic Guides*, 287 Med. Intel. 227 (1972). • Ronald J. Sawchuk et al., *Steady-State Plasma Concentrations as a*	concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of two weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of two weeks after injection. The above list is not meant to be comprehensive.[10] **Intrinsic Evidence** • '122 Patent PH, IDS Enclosure (Feb. 1, 2002). **Extrinsic Evidence** • *Remington's Pharmaceutical Sciences* (Alfonso R. Gennaro ed., 18th ed. 1990). • Howard C. Ansel et al., *Pharmaceutical Dosage Forms And Drug Delivery Systems* 113 (7th ed. 1999). • Plaintiffs' Responses to Defendant Sandoz's Invalidity Contentions;	least 2.5 ngml-1 for the entirety of two weeks; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of two weeks. **Intrinsic Evidence** • '122 Patent col.5, ll.25-35. • '122 Patent col.6, ll.1-17. • '122 Patent col.8, ll.31-32. • '122 Patent col.8, l.65 – col.9, l.14. • '122 Patent col.10, ll.24-55. • '122 Patent, fig.1. • '160 Patent col.5, ll.37-46. • '160 Patent col.6, ll.13-30. • '160 Patent col.8, ll.49-51. • '160 Patent col.9, ll.14-23. • '160 Patent col.10, ll.47-58. • '160 Patent, fig.1. • '680 Patent col.5, ll.54-63. • '680 Patent col.6, ll.28-43. • '680 Patent col.8, ll.58-60. • '680 Patent col.9, ll.21-36. • '680 Patent col.10, ll.43-51. • '680 Patent, fig.1.

[10] *See supra* note 8, incorporated by reference herein.

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	Function of the Absorption Rate and Dosing Interval for Drugs Exhibiting Concentration-Dependent Clearance: Consequences for Phenytoin Therapy, 7 J. Pharma. Biopharma. 543 (1979). • J. Zuidema et al., *Release and absorption rate aspects of intramuscularly injected pharmaceuticals*, 47 Int'l J. Pharma. 1 (1988). • J. Zuidema et al., *Release and absorption rate aspects of intramuscularly injected pharmaceuticals (II)*, 105 Int'l J. Pharma. 189 (1994). • U.S. Patent No. 5,980,945. • U.S. Patent No. 5,434,146. • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels, and that "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml-1 is attained for at least 2 weeks after injection" in the context of the intrinsic	Plaintiffs' Disclosure of Infringement Contentions. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term. • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels. • If necessary, an expert(s) will testify that "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml-1 is attained for at least 2 weeks after injection" did not have a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify that "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml-1 is attained for at least 2 weeks after injection" had multiple meanings to a person	• '139 Patent col.5, ll.35-45. • '139 Patent col.6, ll.11-26. • '139 Patent col.8, ll.34-37. • '139 Patent col.8, l.65 – col.9, l.13. • '139 Patent col.10, ll.23-33. • '139 Patent, fig.1. • '160 Patent PH, Amendment (Aug. 21, 2008). • '680 Patent PH, Office Action (Dec. 21, 2010). • Anthony Howell et al., *Pharmacokinetics, Pharmacological and Antitumour Effects of the Specific Anti-Oestrogen ICI 182780 in Women with Advanced Breast Cancer*, 74 Brit. J. Cancer 300, 302 (1996). **Extrinsic Evidence** • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	evidence, including the evidence referred to above and consistent with the ordinary meaning, means "the blood plasma fulvestrant concentration of at least 2.5 ngml-1 is achieved and maintained for at least 2 weeks." • If necessary, an expert(s) will testify that "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" had a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.	of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence.	
"wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks (after	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks" *See evidence for "whereby a therapeutically significant blood*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-	There are a number of concepts associated with the plain and ordinary meaning, including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
injection)"	*plasma fulvestrant concentration of at least 2.5 ngml-1 is attained for at least 2 weeks after injection" above.* **Extrinsic Evidence** • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels, and that "wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks after injection" in the context of the intrinsic evidence, including the evidence referred to above and consistent with the ordinary meaning, means "the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks." • If necessary, an expert(s) will testify that "wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks after injection" had a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the	1 is achieved by the patient in question at any point within four weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any number of points within four weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is maintained by the patient in question for the entirety of four weeks after injection; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by the patient in question for the entirety of four weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of four weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient	any point within four weeks; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any number of points within four weeks; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is maintained by any patient for the entirety of four weeks; • whereby a therapeutically effective blood plasma concentration of an average of at least 2.5 ngml-1 is achieved by any patient for the entirety of four weeks; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of four weeks; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of four weeks.

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.	population is at least 2.5 ngml-1 for the entirety of four weeks after injection. The above list is not meant to be comprehensive.[11] **Intrinsic Evidence** • '122 Patent PH, IDS Enclosure (Feb. 1, 2002). **Extrinsic Evidence** • *Remington's Pharmaceutical Sciences* (Alfonso R. Gennaro ed., 18th ed. 1990). • Howard C. Ansel et al., *Pharmaceutical Dosage Forms And Drug Delivery Systems* 113, 115, 140 (7th ed. 1999). • Plaintiffs' Responses to Defendant Sandoz's Invalidity Contentions; Plaintiffs' Disclosure of Infringement Contentions • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.	**Intrinsic Evidence** • '122 Patent col.5, ll.25-35. • '122 Patent col.6, ll.1-17. • '122 Patent col.8, ll.31-32. • '122 Patent col.8, l.65 – col.9, l.14. • '122 Patent col.10, ll.24-55. • '122 Patent, fig.1. • '160 Patent col.5, ll.37-46. • '160 Patent col.6, ll.13-30. • '160 Patent col.8, ll.49-51. • '160 Patent col.9, ll.14-23. • '160 Patent col.10, ll.47-58. • '160 Patent, fig.1. • '680 Patent col.5, ll.54-63. • '680 Patent col.6, ll.28-43. • '680 Patent col.8, ll.58-60. • '680 Patent col.9, ll.21-36. • '680 Patent col.10, ll.43-51. • '680 Patent, fig.1. • '139 Patent col.5, ll.35-45. • '139 Patent col.6, ll.11-26. • '139 Patent col.8, ll.34-37. • '139 Patent col.8, l.65 – col.9, l.13. • '139 Patent col.10, ll.23-33. • '139 Patent, fig.1. • '160 Patent PH, Amendment

[11] *See supra* note 8, incorporated by reference herein.

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		• If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels. • If necessary, an expert(s) will testify that "wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks after injection" did not have a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify that "wherein the blood plasma fulvestrant concentration is attained for at least 4 weeks after injection" had multiple meanings to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence.	(Aug. 21, 2008). • '680 Patent PH, Office Action (Dec. 21, 2010). • Anthony Howell et al., *Pharmacokinetics, Pharmacological and Antitumour Effects of the Specific Anti-Oestrogen ICI 182780 in Women with Advanced Breast Cancer*, 74 Brit. J. Cancer 300, 302 (1996). **Extrinsic Evidence** • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.
"wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks (after injection)"	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for 2 to 5 weeks." *See evidence for "whereby a therapeutically significant blood*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-	There are a number of concepts associated with the plain and ordinary meaning, including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	plasma fulvestrant concentration of at least 2.5 ngml^{-1} is attained for at least 2 weeks after injection" above. **Extrinsic Evidence** • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels, and that "wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks after injection" in the context of the intrinsic evidence, including the evidence referred to above and consistent with the ordinary meaning, means "the blood plasma fulvestrant concentration of at least 2.5 ngml-1 is achieved and maintained for 2 to 5 weeks." • If necessary, an expert(s) will testify that "wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks after injection" had a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence.	1 is achieved by the patient in question at any point beginning two weeks after injection and ending at five weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any number of points beginning two weeks after injection and ending at five weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is maintained by the patient in question for the entirety of the time beginning two weeks after injection and ending at five weeks after injection; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by the patient in question for the entirety of the time beginning two weeks after injection and ending at five weeks after injection; • whereby the mean therapeutically	any point within two to five weeks; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any number of points within two to five weeks; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is maintained by any patient for the entirety of the time between two to five weeks; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by any patient for the entirety of the time between two to five weeks; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of two to five weeks; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1

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'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	• If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.	effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of the time beginning two weeks after injection and ending at five weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of the time beginning two weeks after injection and ending at five weeks after injection. The above list is not meant to be comprehensive.[12] **Intrinsic Evidence** • '122 Patent PH, IDS Enclosure (Feb. 1, 2002). **Extrinsic Evidence** • *Remington's Pharmaceutical Sciences* (Alfonso R. Gennaro ed., 18th ed. 1990). • Howard C. Ansel et al.,	for the entirety of two to five weeks. **Intrinsic Evidence** • '122 Patent col.5, ll.25-35. • '122 Patent col.6, ll.1-17. • '122 Patent col.8, ll.31-32. • '122 Patent col.8, l.65 – col.9, l.14. • '122 Patent col.10, ll.24-55. • '122 Patent, fig.1. • '160 Patent col.5, ll.37-46. • '160 Patent col.6, ll.13-30. • '160 Patent col.8, ll.49-51. • '160 Patent col.9, ll.14-23. • '160 Patent col.10, ll.47-58. • '160 Patent, fig.1. • '680 Patent col.5, ll.54-63. • '680 Patent col.6, ll.28-43. • '680 Patent col.8, ll.58-60. • '680 Patent col.9, ll.21-36. • '680 Patent col.10, ll.43-51. • '680 Patent, fig.1. • '139 Patent col.5, ll.35-45. • '139 Patent col.6, ll.11-26. • '139 Patent col.8, ll.34-37. • '139 Patent col.8, l.65 – col.9, l.13.

[12] *See supra* note 8, incorporated by reference herein.

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		Pharmaceutical Dosage Forms And Drug Delivery Systems 113 (7th ed. 1999). • Plaintiffs' Responses to Defendant Sandoz's Invalidity Contentions; Plaintiffs' Disclosure of Infringement Contentions. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term. • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels. • If necessary, an expert(s) will testify that "wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks (after injection)" did not have a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify that "wherein the blood plasma fulvestrant concentration is attained for 2 to 5 weeks (after	• '139 Patent col.10, ll.23-33. • '139 Patent, fig.1. • '160 Patent PH, Amendment (Aug. 21, 2008). • '680 Patent PH, Office Action (Dec. 21, 2010). • Anthony Howell et al., *Pharmacokinetics, Pharmacological and Antitumour Effects of the Specific Anti-Oestrogen ICI 182780 in Women with Advanced Breast Cancer*, 74 Brit. J. Cancer 300, 302 (1996). **Extrinsic Evidence** • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.

EXHIBIT A

'122 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		injection)" had multiple meanings to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence.	

EXHIBIT B

'160 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"hormonal dependent benign or malignant disease of the breast or reproductive tract"	Plain and ordinary meaning to a person of skill in the art. *See evidence for "hormonal dependent benign or malignant disease of the breast or reproductive tract" in the '122 Patent.*	Various words of phrases within the claim term have a plain and ordinary meaning. However, the arrangement of the words within this claim term renders the term "benign or malignant disease" to be redundant. To the extent that this term is not redundant, the claim term is indefinite. Moreover, "hormonal dependent" is a term of degree. The Federal Circuit has held that for terms of degree, they must be defined or clarified in the specification or claim to identify more than merely *some* standard for measuring the scope of the term of degree phrase, and that a failure to do so renders the term indefinite. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014). Here, the specification and claim renders no guidance as to the scope of hormonal dependency required, instead, it depends on the unpredictable vagaries of any one person's opinion; therefore, the claim term is indefinite. *Id.* at 1371. *See evidence for "hormonal dependent benign or malignant*	Certain terms and phrases have a plain and ordinary meaning, while other terms and phrases, for example, "hormonal dependent" and/or "disease of the breast or reproductive tract" are indefinite in light of failure of the intrinsic record to provide necessary guidance as to the scope and meaning of these terms and phrases. *See evidence for "hormonal dependent benign or malignant disease of the breast or reproductive tract" in the '122 Patent.*

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'160 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		disease of the breast or reproductive tract" in the '122 Patent.	
"administration to a human in need of such treatment"	Plain and ordinary meaning to a person of skill in the art—i.e., administration to a human with a disease (as limited by the claims) that could benefit from the method of treating. *See evidence for "hormonal dependent benign or malignant disease of the breast or reproductive tract" and "administration to a human in need of such treatment" in the '122 Patent.*	Plain and ordinary meaning – i.e., administration to a human having a hormonal dependent benign or malignant disease of the breast or reproductive tract. *See evidence for "administration to a human in need of such treatment" in the '122 Patent.*	Plain and ordinary meaning – i.e., administration to a human having a hormonal dependent benign or malignant disease of the breast or reproductive tract. To the extent "in need of such treatment" refers to "hormonal dependent benign or malignant disease of the breast or reproductive tract," Sagent incorporates its proposed constructions and intrinsic/extrinsic evidence citations accordingly. *See evidence for "administration to a human in need of such treatment" in the '122 Patent.*
"fulvestrant"	Plain and ordinary meaning to a person of skill in the art—i.e., the international non-proprietary name for the chemical compound, 7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol. *See evidence for "fulvestrant" in the*	"7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol, including pharmaceutically acceptable salts thereof, and any possibly solvates of either thereof" *See evidence for "fulvestrant" in the '122 Patent.*	"Fulvestrant (7α-[9-(4,4,5,5,5-pentafluropentylsulphinyl0nonyl]oestra-1,3,5(10)-triene-3,17β-diol) or a pharmaceutically acceptable salt or solvate thereof" *See evidence for "fulvestrant" in the '122 Patent.*

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'160 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	'122 Patent.		
"from 8.5 to 11.5%" (weight of ethanol per volume of formulation)	"from 8.5 to 11.5%" (weight of pharmaceutically-acceptable ethanol per volume of formulation) *See evidence for "10% weight of ethanol per volume of formulation" in the '122 Patent.*	"from exactly 8.5% (weight of ethanol per volume of formulation) to exactly 11.5%" (weight of ethanol per volume of formulation) *See evidence for "10% weight of ethanol per volume of formulation" in the '122 Patent.*	
"ethanol"	"pharmaceutically-acceptable ethanol of a quality such that it will meet pharmacopoeial standards (such as are described in the US, British, European and Japanese pharmacopoeias) and as such will contain some water and possibly other organic solvents, for example ethanol in the US Pharmacopeia contains not less than 94.9% by volume and not more than 96.0% by volume of ethanol when measured at 15.56° C, and dehydrated alcohol in the US Pharmacopeia contains not less than 99.5% ethanol by volume when measured at 15.56° C." *See evidence for "ethanol" in the '122 Patent.*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • Pure ethanol; • ethanol containing "some water"; • ethanol containing "some other solvents"; • ethanol containing "some water" and "some other solvents"; • not less than 92.3 percent and not more than 93.8 percent, by weight, corresponding to not less than 94.9 percent and not more than 96.0 percent, by volume, at 15.56°, of C_2H_5OH; • not less than 99.2 percent, by weight, corresponding to not less than 99.5 percent, by volume, at 15.56°, of C_2H_5OH; • not less than 95.1 per cent *V/V*	There are a number of concepts associated with the plain and ordinary meaning of ethanol, including but not limited to C_2H_5OH, dehydrated or pure ethanol, alcohol USP, alcohol USP, $\geq$ 99.5% v/v of C_2H_5OH, 95.1-95.6% v/v (by specific gravity) of C_2H_5OH at 15° C, or any common used form of ethanol or alcohol including in combination with various amounts of water and other solvents. *See evidence for "ethanol" in the '122 Patent.*

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'160 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		(92.6 per cent *m/m*) and not more than 96.9 per cent *V/V* (95.2 per cent *m/m*) of C_2H_6O (M_r 46.07) at 20°C, and water; • not less than 99.4% v/v or 99.0% w/w and not more than 100.0% v/v or 100.0% w/w of C_2H_5OH; • not less than 95.1 vol% and not more than 95.6 vol% (by specific gravity) of C_2H_6O at 15° C. The above list is not meant to be comprehensive.[13] *See evidence for "ethanol" in the '122 Patent.*	
"from 8.5 to 11.5%" (weight of benzyl alcohol per volume of formulation)	"from 8.5 to 11.5%" (weight of pharmaceutically-acceptable benzyl alcohol per volume of formulation) *See evidence for "10% weight of ethanol per volume of formulation" and "10% weight of benzyl alcohol per volume of formulation" in the '122 Patent.*	"from exactly 8.5% (weight of benzyl alcohol per volume of formulation) to exactly 11.5%" (weight of benzyl alcohol per volume of formulation) *See evidence for "10% weight of ethanol per volume of formulation" in the '122 Patent.*	
"12 to 18%" (weight of benzyl benzoate	"12 to 18%" (weight of pharmaceutically-acceptable benzyl benzoate per volume of formulation)	"exactly 12% (weight of benzyl benzoate per volume of formulation) to exactly 18%" (weight of benzyl	

[13] *See supra* note 8, incorporated by reference herein.

EXHIBIT B

'160 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
per volume of formulation)	*See evidence for "10% weight of ethanol per volume of formulation" and "15% weight of benzyl benzoate per volume of formulation" in the '122 Patent.*	benzoate per volume of formulation) *See evidence for "10% weight of ethanol per volume of formulation" in the '122 Patent.*	
"sufficient amount of a castor oil vehicle"	"after fulvestrant and the excipients, the remaining volume is filled with pharmaceutically-acceptable castor oil" *See evidence for "sufficient amount of a castor oil vehicle" in the '122 Patent.*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • sufficient amount of a castor oil to solubilize the active ingredient; • sufficient amount of a castor oil to bring the composition to a certain volume; • sufficient amount of a castor oil to bring the composition to a certain weight; • sufficient amount of a castor oil needed to minimize precipitation of the injected formulation; • sufficient amount of a castor oil needed to render the injected formulation functional; • sufficient amount of a castor oil containing a particular proportion of triglycerides of ricinoleic acid; • sufficient amount of a particular grade of castor oil; • sufficient amount of a castor oil	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • sufficient amount of a castor oil to solubilize the active ingredient; • sufficient amount of a castor oil to bring the composition to a certain volume; • sufficient amount of a castor oil needed to minimize precipitation of the injected formulation; • sufficient amount of a castor oil needed to render the injected formulation functional; • sufficient amount of a castor oil containing a particular proportion of triglycerides of ricinoleic acid; • sufficient amount of a particular grade of castor oil; • sufficient amount of a castor oil that conforms to a particular standard; • sufficient amount of a castor oil

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'160 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		that conforms to a particular standard; • sufficient amount of a castor oil blended with other oils. The above list is not meant to be comprehensive.[14] *See evidence for "sufficient amount of a castor oil vehicle" in the '122 Patent.*	blended with other oils. *See evidence for "sufficient amount of a castor oil vehicle" in the '122 Patent.*
"whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks (after injection)"	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 2 weeks" *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any point within two weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any number of points within two weeks after injection; • whereby a therapeutically	There are a number of concepts associated with the plain and ordinary meaning, including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any point within two weeks; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any number of points within two weeks; • whereby a therapeutically effective blood plasma concentration of at least 2.5

[14] *See supra* note 8, incorporated by reference herein.

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'160 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		effective blood plasma concentration of at least 2.5 ngml-1 is maintained by the patient in question for the entirety of two weeks after injection; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by the patient in question for the entirety of two weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of two weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of two weeks after injection. The above list is not meant to be comprehensive.[15] **Intrinsic Evidence**	ngml-1 is maintained by any patient for the entirety of two weeks; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by any patient for the entirety of two weeks; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of two weeks; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of two weeks. *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml^{-1} is attained for at least 2 weeks after injection" in the '122 Patent.*

[15] *See supra* note 8, incorporated by reference herein.

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'160 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		• Anthony Howell et al., *Pharmacokinetics, Pharmacological and Antitumour Effects of the Specific Anti-Oestrogen ICI 182780 in Women with Advanced Breast Cancer*, 74 Brit. J. Cancer 300 (1996). **Extrinsic Evidence** • *Remington's* Pharmaceutical Sciences (Alfonso R. Gennaro ed., 18th ed. 1990). • Howard C. Ansel et al., *Pharmaceutical Dosage Forms And Drug Delivery Systems* 113 (7th ed. 1999). • Plaintiffs' Responses to Defendant Sandoz's Invalidity Contentions; Plaintiffs' Disclosure of Infringement Contentions. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term. • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels.	

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'160 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		• If necessary, an expert(s) will testify that "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml-1 is attained for at least 2 weeks (after injection)" did not have a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify that "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml-1 is attained for at least 2 weeks (after injection)" had multiple meanings to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence.	

EXHIBIT C

'680 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"hormonal dependent benign or malignant disease of the breast or reproductive tract"	Plain and ordinary meaning to a person of skill in the art. *See evidence for "hormonal dependent benign or malignant disease of the breast or reproductive tract" in the '122 Patent.*	Various words of phrases within the claim term have a plain and ordinary meaning. However, the arrangement of the words within this claim term renders the term "benign or malignant disease" to be redundant. To the extent that this term is not redundant, the claim term is indefinite. Moreover, "hormonal dependent" is a term of degree. The Federal Circuit has held that for terms of degree, they must be defined or clarified in the specification or claim to identify more than merely *some* standard for measuring the scope of the term of degree phrase, and that a failure to do so renders the term indefinite. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014). Here, the specification and claim renders no guidance as to the scope of hormonal dependency required, instead, it depends on the unpredictable vagaries of any one person's opinion; therefore, the claim term is indefinite. *Id.* at 1371. *See evidence for "hormonal dependent benign or malignant disease of the*	Certain terms and phrases have a plain and ordinary meaning, while other terms and phrases, for example, "hormonal dependent" and/or "disease of the breast or reproductive tract" are indefinite in light of failure of the intrinsic record to provide necessary guidance as to the scope and meaning of these terms and phrases. *See evidence for "hormonal dependent benign or malignant disease of the breast or reproductive tract" in the '122 Patent.*

EXHIBIT C

'680 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		breast or reproductive tract" in the '122 Patent.	
"a human in need of such treatment"	Plain and ordinary meaning to a person of skill in the art—i.e., a human with a disease (as limited by the claims) that could benefit from the method of treating. *See evidence for "hormonal dependent benign or malignant disease of the breast or reproductive tract" and "administration to a human in need of such treatment" in the '122 Patent.*	Plain and ordinary meaning – i.e., a human having a hormonal dependent benign or malignant disease of the breast or reproductive tract. *See evidence for "administration to a human in need of such treatment" in the '122 Patent.*	Plain and ordinary meaning – i.e., a human having a hormonal dependent benign or malignant disease of the breast or reproductive tract. To the extent "in need of such treatment" refers to "hormonal dependent benign or malignant disease of the breast or reproductive tract," Sagent incorporates its proposed constructions and intrinsic/extrinsic evidence citations accordingly. *See evidence for "administration to a human in need of such treatment" in the '122 Patent.*
"formulation"	Plain and ordinary meaning to a person of skill in the art, i.e., pharmaceutical formulation. **Intrinsic Evidence** • The claims provide context and are self-limiting as the "method of treatment" requires administering a "formulation" "intramuscularly" to "a human in need of such	Plain and ordinary meaning **Intrinsic Evidence** • '122 Patent col.1, ll.8-25. • '122 Patent col.5, ll.44-47. **Extrinsic Evidence** If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the	Plain and ordinary meaning **Intrinsic Evidence** • '122 Patent col.1, ll.8-25. • '122 Patent col.5, ll.44-47. • '160 Patent col.1, ll.10-16. • '160 Patent col.5, ll.57-60. • '680 Patent col.6, ll.5-8. • '139 Patent col.5, ll.54-57. **Extrinsic Evidence**

EXHIBIT C

'680 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	treatment" • '122 Patent col.6, ll.1-6. • '122 Patent col.11, ll.1-3, 18-22. • '122 Patent PH, Second Information Disclosure Statement (Sept. 13, 2002). • '160 Patent PH, Response (Aug. 21, 2008). • '160 Patent PH, Declaration (Aug. 21, 2008). **Extrinsic Evidence** • Michael J. Akers, *Challenges in the Development of Injectable Products, in Injectable Drug Development: Techniques to Reduce Pain and Irritation* 3-15 (Pramod K. Gupta & Gayle A. Brazeau eds., 1999). • Ansel, 60-100. • Ansel, 397-449. • Stanley L. Hem et al., *Tissue Irritation Evaluation of Potential Parenteral Vehicles*, 1 Drug Dev. Comm. 471 (1975). • If necessary, an expert(s) will testify as to the plain and ordinary meaning of "formulation" in the context of the intrinsic evidence, including	construction of this term.	• If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.

EXHIBIT C

'680 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	the evidence referred to above, and the expert(s) may discuss background on the pharmaceutical formulation process, pharmaceutical formulations and medicinal preparations composed of pharmaceutically-acceptable excipients that safely deliver active ingredients for use in medical therapy. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Defendants regarding the construction of this term.		
"fulvestrant"	Plain and ordinary meaning to a person of skill in the art—i.e., the international non-proprietary name for the chemical compound, 7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol. *See evidence for "fulvestrant" in the '122 Patent.*	"7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol, including pharmaceutically acceptable salts thereof, and any possibly solvates of either thereof" *See evidence for "fulvestrant" in the '122 Patent.*	"Fulvestrant (7α-[9-(4,4,5,5,5-pentafluropentylsulphinyl0nonyl]oestra-1,3,5(10)-triene-3,17β-diol) or a pharmaceutically acceptable salt or solvate thereof" *See evidence for "fulvestrant" in the '122 Patent.*
"ethanol"	"pharmaceutically-acceptable ethanol of a quality such that it will meet pharmacopoeial standards (such as	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited	There are a number of concepts associated with the plain and ordinary meaning of ethanol, including but not

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	are described in the US, British, European and Japanese pharmacopoeias) and as such will contain some water and possibly other organic solvents, for example ethanol in the US Pharmacopeia contains not less than 94.9% by volume and not more than 96.0% by volume of ethanol when measured at 15.56° C, and dehydrated alcohol in the US Pharmacopeia contains not less than 99.5% ethanol by volume when measured at 15.56° C." *See evidence for "ethanol" in the '122 Patent.*	to: • Pure ethanol; • ethanol containing "some water"; • ethanol containing "some other solvents"; • ethanol containing "some water" and "some other solvents"; • not less than 92.3 percent and not more than 93.8 percent, by weight, corresponding to not less than 94.9 percent and not more than 96.0 percent, by volume, at 15.56°, of C_2H_5OH; • not less than 99.2 percent, by weight, corresponding to not less than 99.5 percent, by volume, at 15.56°, of C_2H_5OH; • not less than 95.1 per cent *V/V* (92.6 per cent *m/m*) and not more than 96.9 per cent *V/V* (95.2 per cent *m/m*) of C_2H_6O (M_r 46.07) at 20°C, and water; • not less than 99.4% v/v or 99.0% w/w and not more than 100.0% v/v or 100.0% w/w of C_2H_5OH; • not less than 95.1 vol% and not more than 95.6 vol% (by specific gravity) of C_2H_6O at 15° C. The above list is not meant to be	limited to C_2H_5OH, dehydrated or pure ethanol, alcohol USP, alcohol USP, ≥ 99.5% v/v of C2H5OH, 95.1-95.6% v/v (by specific gravity) of C_2H_5OH at 15° C, or any common used form of ethanol or alcohol including in combination with various amounts of water and other solvents. *See evidence for "ethanol" in the '122 Patent.*

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		comprehensive.[16] *See evidence for "ethanol" in the '122 Patent.*	
"sufficient amount of castor oil vehicle"	"after fulvestrant and the excipients, the remaining volume is filled with pharmaceutically-acceptable castor oil" *See evidence for "sufficient amount of a castor oil vehicle" in the '122 Patent.*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • sufficient amount of a castor oil to solubilize the active ingredient; • sufficient amount of a castor oil to bring the composition to a certain volume; • sufficient amount of a castor oil to bring the composition to a certain weight; • sufficient amount of a castor oil needed to minimize precipitation of the injected formulation; • sufficient amount of a castor oil needed to render the injected formulation functional; • sufficient amount of a castor oil containing a particular proportion of triglycerides of ricinoleic acid; • sufficient amount of a particular grade of castor oil; • sufficient amount of a castor oil	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • sufficient amount of a castor oil to solubilize the active ingredient; • sufficient amount of a castor oil to bring the composition to a certain volume; • sufficient amount of a castor oil needed to minimize precipitation of the injected formulation; • sufficient amount of a castor oil needed to render the injected formulation functional; • sufficient amount of a castor oil containing a particular proportion of triglycerides of ricinoleic acid; • sufficient amount of a particular grade of castor oil; • sufficient amount of a castor oil that conforms to a particular standard; • sufficient amount of a castor oil

[16] *See supra* note 8, incorporated by reference herein.

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'680 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		that conforms to a particular standard; • sufficient amount of a castor oil blended with other oils. The above list is not meant to be comprehensive.[17] *See evidence for "sufficient amount of a castor oil vehicle" in the '122 Patent.*	blended with other oils. *See evidence for "sufficient amount of a castor oil vehicle" in the '122 Patent.*
"wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least four weeks"	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks" *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any point within four weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any number of points within four weeks after injection; • whereby a therapeutically effective blood plasma concentration of at	There are a number of concepts associated with the plain and ordinary meaning, including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any point within a four week timeframe during the course of treatment; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any number of points within a four week timeframe during the course of treatment;

[17] *See supra* note 8, incorporated by reference herein.

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		least 2.5 ngml-1 is maintained by the patient in question for the entirety of four weeks after injection; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by the patient in question for the entirety of four weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of four weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of four weeks after injection. The above list is not meant to be comprehensive.[18] **Intrinsic Evidence** • Anthony Howell et al.,	• whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is maintained by any patient for the entirety of four weeks during the course of treatment; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by any patient for the entirety of four weeks during the course of treatment; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of four weeks during the course of treatment; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of four weeks during the course of treatment. *See evidence for "whereby a*

[18] *See supra* note 8, incorporated by reference herein.

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		Pharmacokinetics, Pharmacological and Antitumour Effects of the Specific Anti-Oestrogen ICI 182780 in Women with Advanced Breast Cancer, 74 Brit. J. Cancer 300 (1996). **Extrinsic Evidence** • *Remington's* Pharmaceutical Sciences (Alfonso R. Gennaro ed., 18th ed. 1990). • Howard C. Ansel et al., *Pharmaceutical Dosage Forms And Drug Delivery Systems* 113 (7th ed. 1999). • Plaintiffs' Responses to Defendant Sandoz's Invalidity Contentions; Plaintiffs' Disclosure of Infringement Contentions. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term. • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels. • If necessary, an expert(s) will	*therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml^{-1} is attained for at least 2 weeks after injection" in the '122 Patent.*

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		testify that "wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml-1 for at least four weeks" did not have a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify that "wherein the method achieves a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml-1 for at least four weeks had multiple meanings to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence.	
"wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 $ngml^{-1}$"	"the blood plasma fulvestrant concentration of at least 8.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks" *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 8.5 ngml-1 is achieved by the patient in question at any point within four weeks after injection; • whereby a therapeutically effective	There are a number of concepts associated with the plain and ordinary meaning, including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 8.5 ngml-1 is achieved by any patient at any point within a four week timeframe during the course of treatment;

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
	'122 Patent.	blood plasma concentration of at least 8.5 ngml-1 is achieved by the patient in question at any number of points within four weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 8.5 ngml-1 is maintained by the patient in question for the entirety of four weeks after injection; • whereby a therapeutically effective blood plasma concentration of an average of at 8.5 ngml-1 is achieved by the patient in question for the entirety of four weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 8.5 ngml-1 for the entirety of four weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 8.5 ngml-1 for the entirety of four weeks after injection. The above list is not meant to be	• whereby a therapeutically effective blood plasma concentration of at least 8.5 ngml-1 is achieved by any patient at any number of points within a four week timeframe during the course of treatment; • whereby a therapeutically effective blood plasma concentration of at least 8.5 ngml-1 is maintained by any patient for the entirety of four weeks during the course of treatment; • whereby a therapeutically effective blood plasma concentration of an average of at 8.5 ngml-1 is achieved by any patient for the entirety of four weeks during the course of treatment; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 8.5 ngml-1 for the entirety of four weeks during the course of treatment; • whereby the mean therapeutically effective blood plasma concentration of a patient

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		comprehensive.[19] **Extrinsic Evidence** • *Remington's* Pharmaceutical Sciences (Alfonso R. Gennaro ed., 18th ed. 1990). • Howard C. Ansel et al., *Pharmaceutical Dosage Forms And Drug Delivery Systems* 113 (7th ed. 1999). • Plaintiffs' Responses to Defendant Sandoz's Invalidity Contentions; Plaintiffs' Disclosure of Infringement Contentions. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term. • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels. • If necessary, an expert(s) will testify that "wherein the therapeutically significant blood plasma fulvestrant concentration is	population is at least 8.5 ngml-1 for the entirety of four weeks during the course of treatment. *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml^{-1} is attained for at least 2 weeks after injection" in the '122 Patent.*

[19] *See supra* note 8, incorporated by reference herein.

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'680 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		at least 8.5 ngml-1" did not have a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify that "wherein the therapeutically significant blood plasma fulvestrant concentration is at least 8.5 ngml-1" had multiple meanings to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence.	

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'139 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"hormonal dependent benign or malignant disease of the breast or reproductive tract"	Plain and ordinary meaning to a person of skill in the art. *See evidence for "hormonal dependent benign or malignant disease of the breast or reproductive tract" in the '122 Patent.*	Various words of phrases within the claim term have a plain and ordinary meaning. However, the arrangement of the words within this claim term renders the term "benign or malignant disease" to be redundant. To the extent that this term is not redundant, the claim term is indefinite. Moreover, "hormonal dependent" is a term of degree. The Federal Circuit has held that for terms of degree, they must be defined or clarified in the specification or claim to identify more than merely *some* standard for measuring the scope of the term of degree phrase, and that a failure to do so renders the term indefinite. *See Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370-71 (Fed. Cir. 2014). Here, the specification and claim renders no guidance as to the scope of hormonal dependency required, instead, it depends on the unpredictable vagaries of any one person's opinion; therefore, the claim term is indefinite. *Id.* at 1371. *See evidence for "hormonal dependent benign or malignant disease of the*	Certain terms and phrases have a plain and ordinary meaning, while other terms and phrases, for example, "hormonal dependent" and/or "disease of the breast or reproductive tract" are indefinite in light of failure of the intrinsic record to provide necessary guidance as to the scope and meaning of these terms and phrases *See evidence for "hormonal dependent benign or malignant disease of the breast or reproductive tract" in the '122 Patent.*

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'139 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		breast or reproductive tract" in the '122 Patent.	
"a human in need of such treatment"	Plain and ordinary meaning to a person of skill in the art—i.e., a human with a disease (as limited by the claim) that could benefit from the method of treating. *See evidence for "hormonal dependent benign or malignant disease of the breast or reproductive tract" and "administration to a human in need of such treatment" in the '122 Patent.*	Plain and ordinary meaning – i.e., administration to a human having a hormonal dependent benign or malignant disease of the breast or reproductive tract. *See evidence for "administration to a human in need of such treatment" in the '122 Patent.*	Plain and ordinary meaning – i.e., administration to a human having a hormonal dependent benign or malignant disease of the breast or reproductive tract. To the extent "in need of such treatment" refers to "hormonal dependent benign or malignant disease of the breast or reproductive tract," Sagent incorporates its proposed constructions and intrinsic/extrinsic evidence citations accordingly. *See evidence for "administration to a human in need of such treatment" in the '122 Patent.*
"formulation"	Plain and ordinary meaning to a person of skill in the art, i.e., pharmaceutical formulation. *See evidence for "formulation" in the '680 Patent.*	Plain and ordinary meaning. *See evidence for "formulation" in the '680 Patent.*	Plain and ordinary meaning *See evidence for "formulation" in the '680 Patent.*

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'139 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
"fulvestrant"	Plain and ordinary meaning to a person of skill in the art—i.e., the international non-proprietary name for the chemical compound, 7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol. *See evidence for "fulvestrant" in the '122 Patent.*	"7α-[9-(4,4,5,5,5-pentafluoropentylsulphinyl)nonyl]oestra-1,3,5(10)-triene-3,17β-diol, including pharmaceutically acceptable salts thereof, and any possibly solvates of either thereof" *See evidence for "fulvestrant" in the '122 Patent.*	"Fulvestrant (7α-[9-(4,4,5,5,5-pentafluropentylsulphinyl0nonyl]oestra-1,3,5(10)-triene-3,17β-diol) or a pharmaceutically acceptable salt or solvate thereof" *See evidence for "fulvestrant" in the '122 Patent.*
"ethanol"	"pharmaceutically-acceptable ethanol of a quality such that it will meet pharmacopoeial standards (such as are described in the US, British, European and Japanese pharmacopoeias) and as such will contain some water and possibly other organic solvents, for example ethanol in the US Pharmacopeia contains not less than 94.9% by volume and not more than 96.0% by volume of ethanol when measured at 15.56° C, and dehydrated alcohol in the US Pharmacopeia contains not less than 99.5% ethanol by volume when measured at 15.56° C." *See evidence for "ethanol" in the '122 Patent.*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • Pure ethanol; • ethanol containing "some water"; • ethanol containing "some other solvents"; • ethanol containing "some water" and "some other solvents"; • not less than 92.3 percent and not more than 93.8 percent, by weight, corresponding to not less than 94.9 percent and not more than 96.0 percent, by volume, at 15.56°, of C_2H_5OH; • not less than 99.2 percent, by weight, corresponding to not less than 99.5 percent, by volume, at 15.56°, of C_2H_5OH;	There are a number of concepts associated with the plain and ordinary meaning of ethanol, including but not limited to C_2H_5OH, dehydrated or pure ethanol, alcohol USP, alcohol USP, ≥ 99.5% v/v of C_2H_5OH, 95.1-95.6% v/v (by specific gravity) of C_2H_5OH at 15° C, or any common used form of ethanol or alcohol including in combination with various amounts of water and other solvents. *See evidence for "ethanol" in the '122 Patent.*

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'139 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		• not less than 95.1 per cent *V/V* (92.6 per cent *m/m*) and not more than 96.9 per cent *V/V* (95.2 per cent *m/m*) of C_2H_6O (M_r 46.07) at 20°C, and water; • not less than 99.4% v/v or 99.0% w/w and not more than 100.0% v/v or 100.0% w/w of C_2H_5OH; • not less than 95.1 vol% and not more than 95.6 vol% (by specific gravity) of C_2H_6O at 15° C. The above list is not meant to be comprehensive.[20] *See evidence for "ethanol" in the '122 Patent.*	
"from 19-21%" (w/v of ethanol and benzyl alcohol)	"from 19-21%" (w/v of pharmaceutically-acceptable ethanol and pharmaceutically-acceptable benzyl alcohol) *See evidence for "10% weight of ethanol per volume of formulation" and "10% weight of benzyl alcohol per volume of formulation" in the '122 Patent.*	"from exactly 19% (w/v of ethanol and benzyl alcohol) to exactly 21%" (w/v of ethanol and benzyl alcohol) *See evidence for "10% weight of ethanol per volume of formulation" in the '122 Patent.*	
"14-16%"	"14-16%" (w/v of pharmaceutically-	"exactly 14% (w/v of benzyl benzoate)	

[20] *See supra* note 8, incorporated by reference herein.

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
(w/v of benzyl benzoate)	acceptable benzyl benzoate) *See evidence for "10% weight of ethanol per volume of formulation" and "15% weight of benzyl benzoate per volume of formulation" in the '122 Patent.*	to exactly 16%" (w/v of benzyl benzoate) *See evidence for "10% weight of ethanol per volume of formulation" in the '122 Patent.*	
"sufficient amount of castor oil vehicle"	"after fulvestrant and the excipients, the remaining volume is filled with pharmaceutically-acceptable castor oil" *See evidence for "sufficient amount of a castor oil vehicle" in the '122 Patent.*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • sufficient amount of a castor oil to solubilize the active ingredient; • sufficient amount of a castor oil to bring the composition to a certain volume; • sufficient amount of a castor oil to bring the composition to a certain weight; • sufficient amount of a castor oil needed to minimize precipitation of the injected formulation; • sufficient amount of a castor oil needed to render the injected formulation functional; • sufficient amount of a castor oil containing a particular proportion of triglycerides of ricinoleic acid; • sufficient amount of a particular grade of castor oil;	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • sufficient amount of a castor oil to solubilize the active ingredient; • sufficient amount of a castor oil to bring the composition to a certain volume; • sufficient amount of a castor oil needed to minimize precipitation of the injected formulation; • sufficient amount of a castor oil needed to render the injected formulation functional; • sufficient amount of a castor oil containing a particular proportion of triglycerides of ricinoleic acid; • sufficient amount of a particular grade of castor oil; • sufficient amount of a castor oil that conforms to a particular standard;

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		• sufficient amount of a castor oil that conforms to a particular standard; • sufficient amount of a castor oil blended with other oils. The above list is not meant to be comprehensive.[21] *See evidence for "sufficient amount of a castor oil vehicle" in the '122 Patent.*	• sufficient amount of a castor oil blended with other oils. *See evidence for "sufficient amount of a castor oil vehicle" in the '122 Patent.*
"wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ for at least two weeks"	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 2 weeks" *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any point within two weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any number of points within two weeks after injection; • whereby a therapeutically effective	There are a number of concepts associated with the plain and ordinary meaning, including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any point within a two week timeframe during the course of treatment; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any number of points within a two week timeframe during the course

[21] *See supra* note 8, incorporated by reference herein.

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Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		blood plasma concentration of at least 2.5 ngml-1 is maintained by the patient in question for the entirety of two weeks after injection; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by the patient in question for the entirety of two weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of two weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of two weeks after injection. The above list is not meant to be comprehensive.[22] **Intrinsic Evidence**	of treatment; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is maintained by any patient for the entirety of two weeks during the course of treatment; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by any patient for the entirety of two weeks during the course of treatment; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of two weeks during the course of treatment; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of two weeks during the course of treatment

[22] *See supra* note 8, incorporated by reference herein.

EXHIBIT D

'139 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		• Anthony Howell et al., *Pharmacokinetics, Pharmacological and Antitumour Effects of the Specific Anti-Oestrogen ICI 182780 in Women with Advanced Breast Cancer*, 74 Brit. J. Cancer 300 (1996). **Extrinsic Evidence** • *Remington's* Pharmaceutical Sciences (Alfonso R. Gennaro ed., 18th ed. 1990). • Howard C. Ansel et al., *Pharmaceutical Dosage Forms And Drug Delivery Systems* 113 (7th ed. 1999). • Plaintiffs' Responses to Defendant Sandoz's Invalidity Contentions; Plaintiffs' Disclosure of Infringement Contentions. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term. • If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels.	*See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml^{-1} is attained for at least 2 weeks after injection" in the '122 Patent.*

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'139 Patent Proposed Claim Constructions and Identification of Evidence Pursuant to L. Pat. R. 4.3(b)

Claim Term	AstraZeneca's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sandoz's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence	Sagent's Proposed Constructions and Citations of Intrinsic and Extrinsic Evidence
		• If necessary, an expert(s) will testify that "wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 ngml-1 for at least two weeks" did not have a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify that "wherein the method achieves a blood plasma fulvestrant concentration of at least 2.5 ngml-1 for at least two weeks" had multiple meanings to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence.	
"wherein . . . the blood plasma fulvestrant concentration is attained for at least 4 weeks"	"the blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is achieved and maintained for at least 4 weeks" *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 $ngml^{-1}$ is attained for at least 2 weeks after injection" in the '122 Patent.*	There are multiple concepts that can be associated with the plain and ordinary meaning(s), including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by the patient in question at any point within four weeks after injection; • whereby a therapeutically effective blood plasma concentration of at	There are a number of concepts associated with the plain and ordinary meaning, including but not limited to: • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is achieved by any patient at any point within a four week timeframe during the course of treatment; • whereby a therapeutically effective blood plasma

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		least 2.5 ngml-1 is achieved by the patient in question at any number of points within four weeks after injection; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is maintained by the patient in question for the entirety of four weeks after injection; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by the patient in question for the entirety of four weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of four weeks after injection; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of four weeks after injection. The above list is not meant to be	concentration of at least 2.5 ngml-1 is achieved by any patient at any number of points within a four week timeframe during the course of treatment; • whereby a therapeutically effective blood plasma concentration of at least 2.5 ngml-1 is maintained by any patient for the entirety of four weeks during the course of treatment; • whereby a therapeutically effective blood plasma concentration of an average of at 2.5 ngml-1 is achieved by any patient for the entirety of four weeks during the course of treatment; • whereby the mean therapeutically effective blood plasma concentration of a patient population is an average of at least 2.5 ngml-1 for the entirety of four weeks during the course of treatment; • whereby the mean therapeutically effective blood plasma concentration of a patient population is at least 2.5 ngml-1 for the entirety of four weeks

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		comprehensive.[23] **Intrinsic Evidence** • Anthony Howell et al., *Pharmacokinetics, Pharmacological and Antitumour Effects of the Specific Anti-Oestrogen ICI 182780 in Women with Advanced Breast Cancer*, 74 Brit. J. Cancer 300, 302 (1996). **Extrinsic Evidence** • *Remington's* Pharmaceutical Sciences (Alfonso R. Gennaro ed., 18th ed. 1990). • Howard C. Ansel et al., *Pharmaceutical Dosage Forms And Drug Delivery Systems* 113 (7th ed. 1999). • Plaintiffs' Responses to Defendant Sandoz's Invalidity Contentions; Plaintiffs' Disclosure of Infringement Contentions. • If necessary, an expert(s) will testify in rebuttal to any expert testimony proffered by Plaintiffs regarding the construction of this term.	during the course of treatment *See evidence for "whereby a therapeutically significant blood plasma fulvestrant concentration of at least 2.5 ngml^{-1} is attained for at least 2 weeks after injection" in the '122 Patent.*

[23] *See supra* note 9, incorporated by reference herein.

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		• If necessary, an expert(s) will testify on background on the pharmaceutical formulation process, including measurements of plasma levels. • If necessary, an expert(s) will testify that "wherein . . . the blood plasma fulvestrant concentration is attained for at least 4 weeks" did not have a clear and definite meaning to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence. • If necessary, an expert(s) will testify that "wherein . . . the blood plasma fulvestrant concentration is attained for at least 4 weeks" had multiple meanings to a person of ordinary skill in the art at the time of the invention in light of the intrinsic and extrinsic evidence.	